INTERPRETATIONS OF COMMUNICATION EXPERIENCES OF PHARMACEUTICAL-SPONSORED CLINICAL EDUCATORS

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Submitted to the faculty of the University Graduate School
in partial fulfillment of the requirements
for the degree
Doctor of Philosophy
in the Department of Communication Studies,
Indiana University

August 2020

Accepted by the Graduate Faculty of Indiana University, in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

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ACKNOWLEDGEMENT

First and foremost, I give thanks to my husband Bryan, who was a steadfast, compassionate, and motivational supporter throughout this entire process. From cooking a disproportionate number of dinners to the extra shifts of dog walking to the encouraging post-it notes that found their way to my desk, you've been there by my side. For those things, and so many others, I am forever grateful.

To my advisor Jennifer, thank you! You were one of the first people in the department with whom I had the pleasure of working—even before actually enrolling in the program. Throughout the last six years, you've guided me patiently, thoughtfully, and wisely. Your critiques were never harsh, but still challenged me to think further and deeper. My skill as a qualitative scholar has blossomed brightly under your mentorship. I also value our friendship; we always took time in our meetings to share family and life anecdotes and stories. I look forward to continuing our relationship as both colleagues and friends.

I extend many warm regards to Sandra and Marianne. You have both been wonderful mentors who have nurtured my appreciation for the beauty and spirit of communication studies. I hope to continue working with you both beyond the tenure of this dissertation as I still have so much more to learn. I also want to thank Dr. Jones, who helped me further my understanding of health informatics and how communication is integral to that field.

To Mark DiCorcia, thank you for starting me down this path many years ago. I'm here because of the gentle nudging you provided. To VMS, thank you for allowing me to talk with your educators and engage them in this study.

Lastly, to the clinical educators…you are AMAZING! Your passion, empathy, tenacity, and grit in the face of many challenges is inspiring. You were a blessing to interview. Your work and efforts are changing lives and changing healthcare.

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This qualitative study explored the communication experiences of clinical educators who provide patient education on behalf of pharmaceutical company sponsors. It investigated how these educators navigate a medical encounter within the domain of three regulatory drivers—on-label compliance, fair-balance presentation, and adverse event reporting. The study used the ecological model of communication in medical encounters and the theory of Communication Privacy Management (CPM) as the lenses for interpreting the data. The main data were telephonic interviews with twenty-six clinical educators who delivered education services for pharmaceutical companies. Member checking, in the form of three post-interview focus groups, was also used.

Seven themes emerged: (a) political/legal contexts factors greatly influenced clinical educators' communication with patients; (b) the influence of factors within this contexts would frequently force educators to experience ethical dilemmas; (c) a new context, the disease and treatment context, emerged from the interviews as having significant influence in the conversation dynamics; (d) educators employed communication strategies to better navigate within the political/legal and disease and treatment context ecological factors; (e) educators believed they needed to establish and maintain trust throughout the engagement process for them to successfully solicit meaningful patient disclosures; (f) educators managed the information disclosed to them by patients using routinized rules as well as changing rules; and (g) educators managed

multiple types of confidant roles with patients including stakeholder, deliberate, and reluctant.

A main implication for this study is that educators feel ethically and morally bound to do whatever was necessary to avoid breaching the trust they established with patients. For some, this attitude prevailed over their obligation to deliver a compliant educational engagement. Hence, pharmaceutical companies need to recognize that for many of their clinical educators, the question of whether to be compliant is not a legal or policy matter. It is a moral and ethical issue.

That being said, educators were also skilled at using communication strategies to navigate through the compliance and disease and treatment barriers that functioned as self-management barriers. Many of those skills often served to influence the way educators created privacy rules and managed privacy decisions related to their patient engagements.

Jennifer J. Bute, PhD, Chair

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Chapter 1: Introduction

A recently published white paper from *eyeforpharma*, a popular pharmaceutical business and trends magazine, proclaimed that the pharmaceutical industry is at the start of a revolution in patient support programs (PSPs) that is about to transform their business model (eyeforpharma Ltd. & S3 Connected Health, 2018). A PSP is an umbrella term that can refer to any type of disease or therapeutic support service or program provided by a health-related organization (e.g. hospital, clinic, physicians' group, disease advocacy group) or industry (e.g. pharmaceutical company, medical device manufacturer, health insurance provider, retail pharmacy chain) (Ganguli et al., 2016). Within the context of pharmaceutical and biotech companies, PSPs assist patients and caregivers in accessing and understanding their prescribed drugs, medical devices, and the diseases for which they are indicated. These programs are frequently viewed within the pharmaceutical and biotech industry as a means for promoting patient engagement and centricity (eyeforpharma Ltd. & S3 Connected Health, 2018) while also helping to increase medication adherence and adoption of other necessary disease self-management behaviors (Ganguli et al., 2016). Examples of the types of services available through PSPs include insurance benefits investigations, copay card reimbursements, product and disease-state education programs, clinical assistance services (i.e. nurse help lines), adherence reminder and tracking tools, and peer and caregiver counseling and support groups (Ganguli et al., 2016; Ocvirk, 2016). The "revolution," as explained by eyeforpharma, is that such programs are evolving beyond small-scale product-specific engagements to be highly customized holistic experiences delivered in collaboration with payers, health systems, and tech companies that support

patients across their entire lives, not just when patients are taking the company's medication (eyeforpharma Ltd. & S3 Connected Health, 2018). In essence, the white paper predicts that pharmaceutical-sponsored clinical and non-clinical support services will play an increased and fundamental role in patients' daily healthcare management.

The present study examines one component of pharmaceutical-sponsored PSPs—product and disease-state education delivered by clinical educators. The literature review that follows explains how these education programs originated as a strategy to combat medication adherence issues, particularly for products with a complex administration process, such as self-injected or self-infused biologics. The role of the pharmaceutical-sponsored clinical educator, as noted in the literature, is defined along with three regulatory factors that impact how those educators deliver educational programs. Two theoretical frameworks are reviewed, the ecological model of communication in medical encounters (Street, 2003) and communication privacy management (CPM) theory (Petronio, 2002). These theories serve as the lens through which the findings were interpreted. Lastly, the research questions that drove the study are identified.

The methods section that follows the literature review explains how and why a qualitative methodology was used to explore the research questions. This section includes a description of the participants, their recruitment and sampling, an overview of the researcher role, an explanation of the data collection process, and a discussion of how the data were analyzed and interpreted within the constructs of the theoretical frameworks.

There are two findings chapters, each one interpreting the data within the context of one of the two theoretical frameworks. The first findings chapter explores the data

using Street's (2003) ecological model of communication in medical encounters. Four themes arose from that interpretation. These were: (1) Political/legal contexts factors, manifested in pharmaceutical industries' compliance regulations, greatly influenced clinical educators' communication with patients; (2) The influence of ecological factors, particularly within the political/legal context, would frequently force educators to experience ethical dilemmas; (3) A sixth context, the disease and treatment context, not previously identified in the ecological model literature, emerged from the interviews as having significant influence in the conversation dynamics between the educator and patient; and (4) Educators employed communication strategies to better navigate within the political/legal and disease and treatment context ecological factors. The second findings chapter explores the data using Petronio's (2002) CPM theory. Three themes arose from that interpretation. These were: (1) Educators believed they needed to establish and maintain trust throughout the engagement process for them to successfully solicit meaningful patient disclosures; (2) Educators managed the information disclosed to them by patients using routinized rules based on core privacy rule decision criteria as well as changing rules based on catalyst privacy rule decision criteria; and (3) Educators managed multiple types of confidant roles with patients including stakeholder, deliberate, and reluctant.

The last chapter is a discussion of the findings as they relate to the theoretical models and the implications they present for the pharmaceutical industry. One of the major constructs that arose from the interpretation of the data was that three ecological factors inherent and unique to the educators' role greatly affected their communication dynamic with patients. Those factors—staying on-label, fair-balance presentation, and

adverse event reporting—were three of the most influential types of industry and government-imposed compliance regulations that shaped educators' beliefs about how they could engage and educate patients. As such, educators often struggled with their need to reconcile the regulatory obligations to the industry that employed them with the professional and ethical orientations that guided their beliefs about patients care. The chapter closes with an explanation of the study's limitations and suggestions for future research.

In summary, pharmaceutical companies are increasing their participation in the public health environment via the expanding role of PSPs. Additionally, as Cegala (2011) notes, the changing social and economic landscape of the country is moving to a model in which patients are assuming greater responsibility for their own care. This means that patients' ability to be active participants in their interpersonal engagements with healthcare providers (HCPs) is of increased importance if they are to be successful in their health management. The increased role that both patients and pharmaceutical-sponsored clinical educators are taking within the larger healthcare domain has implications for both groups. Patients will find themselves needing to engage with a broader and more diverse range of healthcare professionals and resources beyond the traditional healthcare team. This would include clinical educators. As such, there is an increased responsibility and need for understanding how the educators who are facilitating these programs are maintaining equivalent standards of care as traditional healthcare providers. This is especially important given the unique regulatory and sociological factors that impact these educators—factors that are not faced by a patient's formal healthcare team. A goal of the current study is to interpret within the context of

the two theoretical frameworks how pharmaceutical-sponsored clinical educators navigate the communication complexities that are at the heart of those regulatory and sociological factors. The outcomes of this study can inform the pharmaceutical industry of the perceived impact of regulatory factors on clinical educators' dialogue with patients. In addition, this study will increase pharmaceutical companies' and policy makers' understanding of the communication strategies that are deployed by clinical educators to navigate successfully and compliantly within those factors.

Chapter 2: Review of the Literature

Medication Self-Management Behaviors

Improper self-management behaviors for prescription medication is an endemic problem that impacts the physical, mental, and financial well-being of the individual and society at large. Recent studies has placed non-adherence rates between 25% to 50% for those who take medication (Brixner et al., 2019; Zhou et al., 2018). A far-reaching 2013 survey conducted by the National Community Pharmacists Association (NCPA) estimates that almost one-half of all adults age 40 or over are taking at least one prescription medication for a chronic condition such as hypertension, hyperlipidemia, diabetes, heart problems, or asthma. Of those patients, almost 60% have missed doses while approximately 30% forgot whether they took their medication. Slightly less than 30% did not refill a prescription in time while more than 20% took a lower dose of medication than prescribed. Finally, 15% stopped taking a medication before consulting their healthcare provider (HCP) (National Community Pharmacists Association, 2013). Reasons for non-adherence varied with some of the most popular responses being: 42% said they forgot, 34% ran out of the medication, 27% were away from home, 22% were trying to save money, 21% had problems with side effects, 17% were too busy, 17% felt the prescription was not working, 16% did not think the prescription was needed, and 12% did not like taking the medication.

Adherence rates for common chronic afflictions such as diabetes, osteoporosis, rheumatoid arthritis (RA), psoriasis, and inflammatory bowel disease (IBD), to which there are a wide range of different medications, have similar figures. One study noted that adherence for a popular self-injected medication indicated for treating the

autoimmune conditions of RA, psoriasis, and IBD was approximately 40% (Brixner et al., 2019). Various studies on patients prescribed osteoporosis medications have seen one year discontinuation rates reach between 50% to 75% (Hiligsmann et al., 2013). This is problematic as poor adherence can significantly reduce the bone health gains attributed to these medications while also stifling the cost-effectiveness of proper disease management. Lastly, poor medication adherence is a noted as the primary factor for why 50% of people with diabetes in the United States do not achieve an appropriate A1C level, the metric by which physicians measure average blood glucose levels (Zhou et al., 2018).

The impact of non-adherence can have far-reaching clinical and financial repercussions for the patient and society at large (Brixner et al., 2019; Ganguli et al., 2016). For instance, studies have estimated that non-adherence adds anywhere from an additional $117 to $290 billion annually to U.S. healthcare costs (National Community Pharmacists Association, 2013; National Council on Patient Information and Education, 2007). Equally disturbing is a study that noted that more than 30% of the patients readmitted to a hospital for a chronic condition were there because of non-adherence to their medication (Lam & Fresco, 2015). Reasons for non-adherence are numerous but can be grouped by variable types to include: patient variables such as education, health beliefs, comorbidities, and ability to pay; treatment variables such as medication types, frequencies, side effects, and administration modalities; and variables related to the dynamics of interaction between the patient and the HCP (Briot et al., 2009; Hammond, 1995; Shu et al., 2009). As such, studies have shown that when adherence increases, overall healthcare costs can be lowered (Brixner et al., 2019). Similarly, studies of

patients with diabetes have shown that when adherence rates improve, so too do A1C levels while diabetes-related complications tend to go down (Zhou et al., 2018).

Biologics and self-injection barriers. Adding to the complexity of adherence challenges is that an increasing number of healthcare therapeutic areas are relying on treatments that use large-molecule biologics derived from living cells instead of small-molecule drugs synthesized through a chemical process (Cohen et al., 2006). Most biologics cannot be taken orally and therefore require more invasive and complex procedures for administration, such as self-injection. Self-injected biologics are used to treat a range of some of the most common chronic conditions including diabetes, multiple sclerosis, and inflammatory autoimmune conditions such as ulcerative colitis, Crohn's disease, rheumatoid arthritis, and psoriasis. In fact, since 2010, half or more of the top ten biologics (in sales) are indicated to treat these conditions (Radar, 2011; Stone, 2019; Ubel, 2014).

Unfortunately, issues related to confidence and self-efficacy toward self-injection of biologics are some of the most common patient barriers for adhering to this type of therapy (Brixner et al., 2019). Self-injections create a higher patient burden due to the additional complexity and lifestyle adaptations they require (Lorenzi et al., 2011). These include understanding the correct and safe injection administration protocol, overcoming needle phobias, following special storage, travel, and disposal requirements, and navigating a frequently difficult insurance approval and reimbursement process. Such impediments decrease patients' motivation to speak with their provider regarding self-injectable treatments or seek the educational services that their HCP may provide (Colwell et al., 2005; Lorenzi et al., 2011; Stockl et al., 2010). Finally, insufficient self-

injection training, coaching, and follow-up delivered by HCPs can produce challenges that exacerbate a patient's inability to be adherent (Hicks et al., 2011). However, as with all medications, improvements in biologic adherence can have long-term positive healthcare cost benefits (Brixner et al., 2019).

The Clinical Educator and Patient Support Programs

A popular strategy for helping patients overcome adherence and other barriers to treatment and build self-efficacy toward new therapies is though structured interventions delivered by clinicians specially-trained in patient education Patient-centered educational engagements have been shown to increase initiation of and adherence to a range of treatments, including those that involve self-injection medications for osteoporosis, diabetes, and rheumatoid arthritis (Briot et al., 2009; Lorenzi et al., 2011; Stockl et al., 2010). Through a structured dialogue, a shared understanding between patient and provider can be developed regarding the expectations, limitations, and projected outcomes of treatment (Lindeman, 1995). Most importantly, it is during these conversations that a patient can gain acceptance of their condition and understand the rationale of the required therapy. Only after a patient has accepted the "why" for treatment can behaviors change and the barriers that may slow or impede progress be addressed (Street et al., 2009). Additionally, patient satisfaction with the way a clinician communicates is related to adherence—improved communication leads to better adherence (Duggan & Thompson, 2011).

One format for these educational interventions is patient education delivered by a certified or licensed clinician such as a physician, registered nurse (RN), physician assistant (PA), pharmacist, registered dietitian (RD), clinical therapist, or licensed clinical

social worker (LCSW). These patient education services are frequently cited in the literature as a type or subset of "patient navigation." Individuals who deliver such services are referred to as "patient navigators," "nurse educators," or "clinical educators." Patient navigation has been defined by the National Cancer Institute as "the logistic and emotional support needed to achieve the completion of diagnostic and treatment care" (Freund et al., 2008).

A patient support program (PSP) is a term used to describe a structured disease and therapy self-management support intervention delivered by a clinical educator. These educational programs can be broadly defined though most include individualized medication counseling, training, support, and medication reminders (Ganguli et al., 2016). PSPs can include many different objectives, but most tend to focus on helping patients better manage their diseases and therapies while improving adherence and reducing complications and healthcare costs (Ganguli et al., 2016). Studies have identified PSP programs being implemented by healthcare providers (HCPs), healthcare systems, insurance companies, pharmacy benefits managers (PBMs), and pharmaceutical companies (Brixner et al., 2019; Ganguli et al., 2016). These studies also reported that multiple delivery methods have been employed for PSPs to include individual and group face-to-face interventions as well as telephonic and online engagements.

Much of the literature on clinical educators and PSPs consists of quantitative research that looks at outcomes such as adherence or persistency rates and feasibility analytics (Ganguli et al., 2016; Kelly et al., 2015; McVay et al., 2014). Such programs were found to promote adherence and reduce hospital readmittance, as well as positively support humanistic outcomes, such as improved quality of life and functional status

(Ganguli et al., 2016; Hiligsmann et al., 2013; Zhou et al., 2018). In fact, those programs that included multiple interventions beyond a single session, such as those that included additional education sessions or follow-up medication reminders, were found to be even more effective (Ganguli et al., 2016).

Another frequently measured outcome for PSPs is patient satisfaction scores (Ganguli et al., 2016). However, the way patients define a satisfactory educational interaction can vary. Many patients perceive the quality of time spent teaching to be as important to their satisfaction as the quantity of time in the interpersonal engagement (Alexander et al., 2012; Bartlett et al., 1984; Braddock & Snyder, 2005). Additionally, many patients with chronic conditions feel dissatisfied with how disease and lifestyle information is delivered, particularly in those situations in which a patient perceives the HCP to be rushing through the process. Such frustration often stems from education that consists of an overwhelming amount of information presented in infrequent occurrences. This is at odds with most patients who prefer, and tend to benefit more when, their providers deliver smaller chunks of information over time as part of a continuous process (Hashim, 2017; Wikblad, 1991).

In addition to delivering informational content related to a medication's efficacy and risks, a common goal of PSPs is to empower patients to take ownership of their disease and therapy. This means coaching and motivating them to adopt the sort of self-care behaviors that lead to positive therapeutic outcomes (eyeforpharma Ltd. & S3 Connected Health, 2018; Wolever et al., 2010). The literature has described the process of patient empowerment in varying terms. For example, one frequently used term in the literature is patient activation (Hibbard & Cunningham, 2008; Tolve, 2012; Wolever et

al., 2010). The term is generally understood to refer to individuals' ability and willingness to take on the role of managing their health and healthcare (Hibbard & Cunningham, 2008). Studies have shown that patients' ability to be activated is a result of many factors that may directly or indirectly affect their healthcare experiences. This includes demographic factors such as age, race, ethnicity, education level, and socioeconomic status as well health-related characteristics such as presence of a chronic condition, comorbidities, health insurance type, body mass index (BMI), and self-perceptions of overall health status (Hibbard & Cunningham, 2008). For instance, studies that measure activation have shown that people with chronic conditions are more likely to have lower levels of activation compared to those without. However, those with multiple chronic conditions tend to be more activated than those with only one. High patient activation has been linked to behaviors such as use of preventative care, engaging in healthy behaviors, having clinical indicators within normal ranges, and costing less to insure (Greene & Hibbard, 2012).

Many studies have examined the impact of these PSPs within the context of specific chronic diseases. Some have found conflicting evidence regarding their impact on adherence such as Higligsmann's et al. (2013) review of osteoporosis PSPs, which determined some patients had positive outcomes while others did not. However, most studies related to disease-specific PSPs have documented primarily positive gains. For instance, in a quantitative study of hypertensive patients who were on a long-term drug treatment, researchers found that those who received training about the risks associated with not taking their medication, coupled with multiple follow up visits from a clinical educator, had a longer adherence than those who did not receive the follow-up visits with

training (Saounatsou et al., 2001). Such findings were supportive of a meta-analysis in that same therapeutic area, which determined that education interventions were successful in improving health-related quality of life (HRQoL) for patients with coronary heart disease (Brown et al., 2013). A secondary outcome noted by those researchers was that such interventions reduce subsequent healthcare utilization, which may reduce healthcare costs. Similar positive outcomes were demonstrated for educational interventions in patients with diabetes. One study found that patient education interventions were not only successful in increasing adherence for diabetes treatment, they were a means for strengthening the patient-provider relationship (Rubin, 2005). These stronger bonds led to more regular follow-up visits, that have been shown to be a strong predictor of treatment adherence. Additional findings from that study noted that the educational interventions helped improve diabetes patients' understanding, confidence, and level of self-care toward their disease. Other studies have found that educational interventions were most effective for increasing patients' understanding of the diabetes disease state as well as their adherence rate for dietary regimens and metabolic control (van Dulmen et al., 2007).

Clinical education is particularly impactful for patients who are required to self-inject biologics. One study explained that compliance and discontinuation rates trended toward better outcomes for patients who participated in an extended education program for an injectable diabetes medication (Lorenzi et al., 2011). Similarly, patients who participated in a supplemental disease therapy management (DTM) educational program for an injectable rheumatoid arthritis medication showed significantly higher rates of adherence than those who participated in a routine pharmacy benefits management

(PBM) service. The DTM program included the standard components of the PBM service—welcome brochure, mail-service delivery, refill reminders, and 24-hour pharmacist access. However, the DTM program also provided more robust patient-centric education strategies that included regular consultations with a care coordinator (Stockl et al., 2010).

These studies have clearly shown that patient education programs at the start of treatment are an important step toward adherence. Yet, research also suggests there is a need for ongoing support and even refresher trainings to make sure proper injection techniques are followed. One study noted that because of poor retention of proper injection technique information, many patients incorrectly self-injected. This resulted in adverse outcomes such as lack of site rotation, inaccurate needle depth or angle, improper skin fold technique, insufficient delivery timing, and the formation of fatty lumps that appear at insulin injection sites (Hicks et al., 2011).

The commonality among most studies conducted around medication education is that they have followed a quantitative methodology that examined outcomes related to the patient. Very few studies have approached the concept of pharmaceutical education utilizing a qualitative perspective that explores the role of the clinical educator. This type of interpretive research is best for discovering constructs such as clinical educator engagement, activation, and motivation as well as understanding the nature of the patient-provider relationship from the educator's vantage point. Additionally, pharmaceutical-sponsored clinical educators have a unique role within the healthcare system and are bound by certain regulatory factors that impact how they communicate with patients

during education. While qualitative studies would be appropriate for exploring the relationship between that role and those factors, such studies currently do not exist.

Pharmaceutical-sponsored clinical educators. Many pharmaceutical companies are utilizing clinical educators to provide product and lifestyle education via PSPs (eyeforpharma Ltd. & S3 Connected Health, 2018; Newmark & Blackburn, 2018). Such education programs are especially popular among those companies who manufacture biologics used to treat chronic conditions and those who produce oral medications that have severe side-effect profiles, such as oncolytics, which are self-administered cancer medications (Arrington et al., 2018; Rossheim, 2016). For these programs, patient education is provided by a clinician who is paid by a pharmaceutical or biotech company. Like other PSPs, industry-sponsored programs include product and safety information as well as injection training for self-administered biologics. Program content can be delivered via a range of different formats, including web-conference, telephonic support, and face-to-face engagements. (AbbVie, 2013; Amgen, 2019; Biogen, 2020; NovoNordisk, 2019; Sanofi-Aventis, 2019; UCB, Inc, 2020). In addition to product training, some manufacturers also underwrite or sponsor lifestyle and disease-state management programs that focus on topics such as diet, physical activity, and mental health (NovoNordisk, 2019; UCB, Inc, 2020).

A primary reason pharmaceutical-sponsored education programs are growing in popularity is an outcome of the dissatisfaction some patients feel regarding the length and type of communication they receive from their primary healthcare team regarding their prescribed therapies (Alexander et al., 2012; Bartlett et al., 1984; Ganguli et al., 2016; National Council on Patient Information and Education, 2007). However, there are only

a few studies in the peer-reviewed literature that have examined the outcomes of industry-sponsored PSPs. Most were large-scale and utilized real-time prescription databases that tracked actual fills and refills instead of relying on patient self-reports. One such study examined the impact of a multiple touchpoint PSP delivered by a team of clinical nurse educators for over 2,200 U.S. patients prescribed a popular biologic used to treat chronic autoimmune conditions like RA, psoriasis, and IBD. It used a national claims database to track de-identified prescriptions and found that the participants enrolled in the PSP had a 29% higher adherence rate than those not enrolled and a 22% lower discontinuation rate. Additionally, it noted that disease related medical costs and all-cause medical costs were lower by 35% (Brixner et al., 2019). A study for that same medication was conducted on a telephonic-based version of the PSP in Canada using prescription data from over 10,000 patients. Participants in the PSP were found to have a 72% decreased risk for therapy discontinuation and a greater likelihood for adherence compared to those prescribed the medication but not enrolled in the program (Marshall et al., 2018). Lastly, a 12-month retrospective of patients with Type 2 diabetes looked at outcomes for those enrolled in a PSP for insulin. It found that adherence and persistency increased for patients new to insulin as well as those switching from another brand compared to those not enrolled (Zhou et al., 2018).

Regulatory Factors

There is a difference in a formal patient education program conducted on behalf of a pharmaceutical company compared to one delivered by a patient's primary healthcare team. The former is held to a level of government scrutiny imposed by U.S. Food and Drug Administration (FDA) mandates that limit the scope and way content can

be addressed. Specifically, there are three regulatory-related factors that shape the content and delivery of pharmaceutical-based clinical educators program—staying on-label, fair-balance presentation, and adverse event reporting.

Staying on-label. The primary purpose of an FDA-mandated prescription medication label, also known as the prescribing information or package insert, is to give HCPs the information they need to properly prescribe drugs and biologics (Kremzner & Osborne, 2007). Drug labeling requirements are regulated by Title 21 of U.S. Code of Federal Regulations (CFR) section 201.56 "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" which state that labels must (a) provide a summary of the safe and effective use of the drug, (b) be informative and accurate, (c) be non-promotional and not false or misleading, (d) not imply claims or suggestions for use if evidence of safety or effectiveness is lacking, and (e) when possible, be based on data derived from human experience (U.S. Government Printing Office, 2014). Pharmaceutical companies who violate drug labeling and promotional regulations are subject to a range of penalties. Additionally, violators may be forced into lengthy and expensive Corporate Integrity Agreements (CIA) with the government that require increased scrutiny measures, additional reporting, and regular training (U.S. Office of Inspector General, 2015).

An FDA approved label drives all decisions regarding how a pharmaceutical company markets and promotes a product. All messaging must be supportive of, and verifiable to, the label. Sales representatives, clinical educators, promotional materials, and media may only speak to claims, indications, side effects, safety information, and clinical trial data as noted in the label. As agents of these companies, pharmaceutical-

sponsored clinical educators are therefore held to the same guardrails as sales representatives. They cannot discuss medication-related content outside the scope of the label.

Fair balance presentation. In addition to overseeing the content of the label, the FDA also regulates the way drug and biologic product information is marketed to the public and delivered to potential prescribers. The concept of *fair balance* is a term used to explain the governmental requirement that product promotions must balance claims of *benefits* and *efficacy* with information regarding *risks* and *side effects*. Content must be presented in a way that does not diminish risks through such techniques as obscured or overly small font size, unrealistic imagery of the target patient populations, or rushed explanations of common side effects tacked onto the end of a physician presentation (U.S. Food & Drug Administration, 2015, 2017b).

Additionally, the FDA requires that all subject deaths that occurred during or immediately following clinical trials be included as part of a drug's New Drug Application (NDA) regardless if there was any evidence that directly linked the drug to the cause of death (U.S. Government Printing Office, 2019). Thus, this could result in death being included as a possible serious side effect as part of the Important Safety Information in promotional material.

Adverse event reporting. From clinical trials to post-market launch, adverse event data is collected throughout the lifecycle of a drug. The FDA defines an adverse event as "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related" (U.S. Government Printing Office, 2019). Adverse events can include mild to severe side effects, product use errors, product quality

problems, and therapeutic failures (U.S. Food & Drug Administration, 2017c). As part of the drug's post-marketing safety surveillance program, the FDA requires drug companies to document and track all adverse events each time they are observed or reported through the FDA Adverse Event Reporting System (FAERS) (U.S. Food & Drug Administration, 2017a). In some instances, adverse event data gathered after clinical trials can affect a drug's post-market safety profile. This can result in such consequences as changes to a product's label, FDA-issued safety alerts, or in extreme cases, removal of the product from the market (U.S. Food & Drug Administration, 2014).

Understanding the relationships and influences of these regulatory factors on those responsible for educating patients on medications can best be understood when examined with the context of interpersonal and health communication theories. The following section examines two theoretical frameworks well-suited for this task.

Theoretical Frameworks

Many communication theories that explore the concept of interpersonal engagement in the health environment do so within the context of the individual as a patient and/or caregiver interacting with an HCP (Street & Epstein, 2008). Such is the case of the present study that investigated interpersonal engagements between patients and pharmaceutical-sponsored clinical educators. While these clinical educators are typically not considered part of a patient's primary or "formal" healthcare team, the education, coaching, and psychosocial support they provide is akin to those same services the patient would receive from his or her doctors, nurses, pharmacists, and therapists. Therefore, theories that explore the nature of patient-HCP interpersonal health

communication can provide suitable frameworks for examining the communication complexities clinical educators face when they are engaged in medical encounters.

Two widely used communication frameworks that are relevant to the current study are Street's (2003) ecological model of communication in the medical encounter and Petronio's (2002) Communication Privacy Management (CPM) theory. Street's model is specific to interpersonal *health* communication while Petronio's theory has been applied within the broader context of interpersonal communication. However, both offer a means for interpreting the way regulatory factors influence clinical educator communication engagements and the manner in which educators respond to those dynamics. For instance, Street's ecological model's emphasis on the role of socio-political and demographic contexts in interpersonal health communication provides a suitable lens to explore how industry and government regulations related to staying on-label, fair balance presentation, and adverse event reporting function as influencing factors within a political/legal context. Secondly, CPM describes how confidant role types impact the communication boundaries between a health information discloser and recipient. This serves as an appropriate framework for exploring how patients and clinical educators co-create communication rules and boundaries based on those perceived confidant roles as well as the regulatory factors that impact those boundaries. The following sections describe each theory in greater detail and their relevance to the present study.

Ecological model of communication in medical encounters. Ecological models of communication have been used by health communication researchers to understand the relationship between people and their health. At the heart of an ecological perspective is

the notion that health behaviors cannot be interpreted in isolation of the environmental and policy contexts in which they occur (Sallis et al., 2008). Such perspectives consider that these influences happen simultaneously within multiple levels to include intrapersonal, interpersonal, organizational, community, and public policy (Street, 2003).

Street (2003) examined the variety of ecological factors and influences that can impact the interpersonal patient-provider dialogue within a medical encounter. This is an important consideration as such factors can determine the nature and scope of interpersonal communication. Street separates these factors into four contexts of socio-political and demographic factors that impact and influence both the patient and the HCP and the way their interactions unfold. The culture context is comprised of factors that are descriptive of one's culture, such as race, gender, ethnicity, religion, and socioeconomic status. Street noted that the ecological factors of race and ethnicity are often of high interest for study as they can help understand and alleviate the well documented impact of those types of disparities in healthcare. Additionally, the use of this context as a study lens can serve as means for designing the sort of training programs that improve HCP cultural competencies. The media context includes factors related to the modalities by which communication occurs, such as access to or use of Internet, telemedicine, and mass media exposure. Street specifically highlighted the way the Internet has transformed the interpersonal dynamic between patients and HCPs because of the way it has enabled patients to seek out and come to an interpersonal encounter armed with their own information. He credits this medium as a primary reason for a shift from the traditional physician-centered approach to healthcare communication to one that is oriented around a shared decision-making partnership with patients. The political-legal context is inclusive

of factors that are tied to legislative and judicial actions pertinent to healthcare, such as the Affordable Care Act (ACA) and government-funded healthcare programs (e.g. Medicare, Medicaid), malpractice litigation, and patients' bill of rights. Street posited that because this context was understudied, there is a lack of clarity as to how it could impact patient-provider communication. He asserted that two outcomes were possible, one being that the constant threat of litigation would pressure HCPs to adopt a more cautious and guarded style of interaction with patients. The converse possibility was that HCPs might engage in more patient-centered communication as such behavior styles are thought to lower malpractice risks.

The fourth socio-political context identified by Street (2003) was the organizational context. It includes the influence of structures such as managed cared, the medical services available, and the standards of care that drive those services. When explaining the organizational context, Street (2003) pointed out how factors within a context can function as healthcare barriers by impeding the patient-provider communication dynamic. For example, he examined the impact of the managed care healthcare system, an influencing factor within the organizational context of his model, on patient-provider dialogue. He contended that the frequently diminished trust that is created by the cost-controlled foundation of managed care can inadvertently lead to a more physician-centered communication framework described as paternalistic dialogue. In fact, he questioned whether the ecological influence of health regulations, coupled with the fear of litigation imposed by health payors and insurers, have pressured clinicians to adopt a cautious and guarded style of communication with patients. Such a question is relevant when exploring any theoretical constructs of patient-HCP dialogue as

related to the role of clinical educators. If cost-control and government policy factors of the managed care system has the potential to erode trust and impact a physician's communication dynamics, similar consequences may be possible regarding FDA-mandated regulatory factors on pharmaceutical-sponsored clinical education programs.

Many ecological perspective models used in social science research are similar to Street's (2003) in that they use a framework of socio-political and demographic contexts to explain behavior. However, Street's ecological model of communication in the medical encounter is unique in that it narrows its focus to the interpersonal communication behaviors that exist between an HCP and patient as part of a health-related engagement. As such, Street explains that, in addition to the four socio-political contexts, an interpersonal communication context exists that further impacts how patients and HCPs talk to each other. That context contains two types of influences—cognitive/affective and predispositional.

Street (2003) explains that within any interpersonal interaction, participants create a cognitive representation of the encounter that incorporates their goals, perceptions, appropriate behaviors and the way the engagement will unfold. He characterizes these elements as cognitive/affective influences. These influences account for the situational factors which spur patients and HCPs to adapt their communication for strategic goals and purposes. They also encompass attributional factors, (e.g. perceptions, stereotypes, impressions), relational constructs (e.g. trust, familiarity), and emotional considerations (e.g. fear, anxiety). For example, as Street explained, an HCP who is gregarious and typically engages with patients using shared decision-making tactics, may change that style to a more directive or didactic approach when discussing a difficult prognosis.

Similarly, an individual who typically prefers a collaborative form of engagement with HPCs may seek out a more paternalistic approach from a physician if that individual is serving in the role of a decision maker for an incapacitated friend or family member. Street stresses that such contexts needs further study. He acknowledges that though scholars have a firm understanding of the relationship of socio-political and demographic factors influence on interpersonal communication, they know less about how the interactants' goals, expectations, and perceptions affect what occurs in consultations.

The other factors within Street's (2003) interpersonal context are what he refers to as predispositional influences. These are factors that provide for consistency of communication such as communication style (e.g. expressive, dominant, open, attentive), individual self-concept (e.g. attitudes, beliefs, personality), and access to linguistic resources. For instance, predispositional influences are what a communication scholar might use to describe whether a physician has a patient-centered style of communication (e.g. using open-ended questions, seeking patient input, incorporating counseling behaviors) or a physician-centered style of communication (e.g. using close-ended questions, being directive to patients, focusing strictly on a patient's physical condition). Like cognitive/affective factors, these influences can also drive how patients interact with their HCPs, such as choosing a collaborative style of engagement or seeking a more paternalistic HCP approach in which the provider is more directive.

Other scholars have similarly noted how different types of HCP communication styles can influence the relationship and type of engagement that develops between the HCP and patient. For instance, Emanuel and Emanuel's (1992) four models of the physician-patient relationship categorized the interpersonal health communication

process as it relates to medical decision-making. The paternalistic model is one in which the HCP assumes leadership and management of the dynamic and thereby makes decisions based on what he or she feels is in the best interest of the patient. The inverse of that style is the informative model in which the HCP simply provides information while the patient assumes leadership and management of decisions. The interpretive model, like the informative model, recognizes the need for the physician to provide technical information. However, while the patient is still the decision maker, he or she allows the provider to elucidate their values and assist in the guidance of therapies and medical decisions. Lastly, there is the deliberative model, which is when the patient not only requires technical advice from the HCP, but also help in determining what values are necessary to guide the decision-making process. The provider empowers the patient with both technical knowledge and values, and through dialogue, helps the patient make medical decisions.

The ecological model and ethics. The predispositional influence of communication styles has served as an explanatory lens within multiple studies that examine the ecological model of interpersonal communication within a healthcare context. Many of these studies examined communication style and how its intersection with the medical ethic of autonomy influenced patient preferences and participation in the medical encounter (Cegala, 2011; Street, 2003; Street et al., 2005, 2012). For instance, Street, et al. (2012) explain that patient preferences related to their healthcare "are dynamic and embedded within multiple, interconnected layers of context" (p. 170). As an example, they note that if an HCP has a predispositional communication style in which they always frame a prognosis message for treatment in the context of its efficacy

or positive outcomes (e.g. lives saved), a patient will be more likely to prefer that treatment. Conversely, if the message is framed in the context of the treatment's risks or negative outcomes (e.g. lives lost), the patient will be less likely to prefer it. As the authors also point out, accounting for patients' preferences for care is endemic of good clinical practice as it honors the medical ethic of autonomy. Patient autonomy is critical to three of Emanuel and Emanuel's (1992) four models of models of patient-physician relationships—informative, interpretive, and deliberative. Hence, when an HCP's predispositional communication style is such that it encourages patients to adopt full or shared autonomy in the decision-making process, patients are more likely to articulate their preferences regarding treatment and disease management.

That notion has been the subject of studies by others, including Cegala (2011) and Street et al. (2005). Findings from Cegala's study asserted that physicians' patient-centric communication style significantly predicted active patient participation in the medical encounter. In other words, those physicians who placed value on communication styles that nurtured patient autonomy found that their patients were more actively engaged in discussions, asked more questions, and provided more details about their disease and treatment. Such outcomes were supportive of an earlier study by Street et al., that found patients were more likely to be an active participant in their consultations with physicians when those physicians used partnership-building and other types of supportive communication. They described partnership-building to include such behaviors as asking for a patient's opinion, using open-ended questions, and engaging in reassuring and encouraging dialogue. Conversely, they noted that physicians who utilized a paternalistic style of communication that focused on control would discourage patient participation.

Lastly, scholars have hypothesized that there is an interpersonal health communication context that occurs outside the scope of the patient-provider dyad, which later influences the communication within that dyad. This is the everyday talk that patients have with family, friends, co-workers, strangers, and third-party healthcare-related professionals—those outside the formal healthcare team (Cline, 2011). Casual health dialogue with such "others" has the power to both enable and constrain formal patient-provider conversations (Head & Bute, 2017). This is an important consideration for pharmaceutical-sponsored clinical educators as their role is a nebulous one—straddling the boundary between a formal or primary healthcare team member and an external third-party other. Head and Bute describe multiple ways in which everyday interpersonal health communication serves as an influential ecological factor that impacts the formal conversations patients have with providers. Some of these influences are relevant to the pharmaceutical-sponsored clinical educator's role. For instance, Head and Bute shared that everyday conversations can later influence the dialogue in formal medical encounters by encouraging patients to ask certain questions or seek specific information. Such would be the case for clinical educators who may further catalyze a patient's information-seeking behaviors with a physician because of the educators' inability to broach off-label topics. In fact, the authors specifically cite that an area of necessary future research would be studies that explore the role third parties (i.e. pharmaceutical-sponsored clinical educators) play as ecological factors in the formal patient-provider medical encounter.

Ecological models in chronic disease management. As previously noted, clinical educators are frequently employed by pharmaceutical companies that

manufacture drugs and biologics to treat chronic conditions such as diabetes, arthritis, psoriasis, inflammatory bowel disease, and multiple sclerosis (AbbVie, 2013; Amgen, 2019; Biogen, 2020; NovoNordisk, 2019). Not surprisingly, ecological models are frequently used as a means for understanding the communication dynamics between HCPs and patients with chronic conditions. Ecological perspectives have been employed as road maps for interpreting how patients and HCPs understand, prevent, and manage diseases such as diabetes, HIV, cardiovascular disease, chronic pain, asthma, and dementia (Fisher et al., 2005; Hruschak & Cochran, 2017; McKenzie et al., 2012; Mudd-Martin et al., 2014; Rose & Garwick, 2003; Tan et al., 2014). Such research serves to inform HCPs of the role ecological factors play in patient understanding and management of their disease. Additionally, intervention-based studies have explored the impact and outcomes of education-based strategies that address ecological factors. One example is the Resources and Supports for Self-Management (RSSM) approach developed by The Diabetes Initiative of the Robert Wood Johnson Foundation. RSSM is grounded in the context of social and environmental influences and recognizes that self-management of diabetes is influenced by many layers and dimensions that are ecologically framed within a set of processes and behaviors (Fisher et al., 2005). The authors explain that ecological influences initiated through policy and community factors may filter down to influence family factors which in turn influence individuals within the family (Fisher et al., 2007).

Moreover, demographic characteristics such as gender, race, ethnicity, and community types are frequently examined in conjunction with specific disease types to provide further understanding of the impact of layered ecological domains on interpersonal health communication. For instance, an ecological model has been used to

explain how HIV positive and negative men who have sex with men of color leverage the ecological domains in which they had high power against the ecological domains in which they had low power (Tan et al., 2014). The authors contend that the model helps health professionals understand why an HIV positive individual from a disadvantaged population would leverage sexuality in order to gain access to financial benefits. In other studies of layered ecological domains, rural community life was examined as a factor for helping health professionals understand how that community type impact patients' responses to chronic conditions such as cardiovascular disease and dementia (McKenzie et al., 2012; Mudd-Martin et al., 2014,). Similarly, the role of urban life on American Indian caregivers has been investigated to describe how the interplay of those ecological domains impacted barriers to the management of childhood asthma (Rose & Garwick, 2003). Finally, gender differences in patient-provider communication have been explored within an ecological framework as has the role of adolescence in such conditions as sickle cell disease and sexually transmitted diseases (DiClemente et al., 2005; Hauser & Dorn, 1999; Street, 2002).

Communication Privacy Management (CPM) theory. The four context categories of Street's (2003) ecological model, along with the extension of the model posed by Head and Bute (2017), provide a suitable framework for examining how regulatory factors impact the patient-educator interpersonal dialogue. However, recognizing *how* the impact happens is just one part of understanding the process by which clinical educators navigate the communication complexities of a medical encounter. As noted previously, the ecological influence of regulatory factors has the potential to erode the trust established during a medical encounter (Street, 2003). CPM

theory provides a means for understanding how educators are able to establish and maintain trust, in light of those communication complexities, by focusing on how relationship boundaries are defined and how privacy rules are created (Petronio, 2002). CPM posits that a person has a sense of ownership over their private information that directs how, when, what, and to whom that information will be shared (Petronio, 2002). Thus, that individual will create privacy rules in order to manage and control the sharing of information. Such rules manifest themselves in figurative boundaries of varying thickness. "Thickness" is a metaphor akin to the concept of boundary permeability that describes the degree of comfort and trust an individual is willing to provide to another person regarding the type and amount of disclosed private information. Someone who has high levels of restriction to their information would therefore have thick or impermeable boundaries. Conversely, a person with fewer constraints for information sharing would have thin boundaries and greater permeability (Petronio & Durham, 2008).

CPM theory also accounts for the sharing of information by noting that once an individual discloses information to another, that information is now co-owned (Petronio, 2002). As part of that co-ownership, the discloser and recipient establish privacy rules that govern how that information in managed and subsequently shared with others. The recipient maintains responsibility for upholding the established rules. However, should that person violate the rules, whether purposefully or because of misinterpretation, a condition referred to as privacy turbulence occurs. This means that boundary permeability has changed and, as a result, new rules might need to be established between the discloser and recipient. For instance, if the violation was intentional, such as in a case of deception or betrayal, communication may be disrupted and thin boundaries may

become thick as the discloser limits or stops communication. If the violation was due to miscommunication or misinterpretation of the rules, those rules may be clarified or renegotiated and thin boundary permeability may remain intact going forward (Petronio, 2002; Petronio & Durham, 2008).

Privacy rules. Boundary coordination is the process by which the information discloser and recipient together negotiate rules and establish boundary parameters (Petronio, 2002). Privacy rules, as a concept, are agreements that help both parties understand how the information is managed and to whom is permitted access. Privacy rules are derived from decision criteria related to the individuals' culture, gender, motivations, context, and risk-benefit ratio (Petronio, 2002; 2013). CPM identifies two main types of rule criteria—core criteria and catalyst criteria. Core criteria are described as durable or stable and tend to function in the background with little deliberation or consideration. These criteria are typically influenced or created from outgrowths of cultural expectations, gendered tendencies, personality characteristics, or socializing privacy orientation (Petronio & Durham, 2008). Cultural expectations are privacy values related to an individual's culture whereas gendered tendencies are values resulting from societal expectations of gender identity (Petronio, 2002; 2013). Personality characteristics, as the term would imply, are privacy values related to various tolerances or propensities inherent to an individual's personality. This might include such internalized constructs such as self-efficacy, self-monitoring, or tolerances for ambiguity. Socializing privacy orientations are values that are generated by group affiliations or other socialized experiences (Petronio, 2002; 2013). As such, core criteria are viewed as predictable meaning that the privacy rules a discloser co-creates with one recipient can be

assumed to be similar to another recipient who shares similar criteria attributes (Petronio, 2013). As an example, studies have shown that cultural influences within the African American community impact the manner in which family medical histories are shared that are different compared to white communities (Ashida et al., 2012; Lin et al., 2018; T. Thompson et al., 2013). Therefore, a healthcare provider would be inclined to solicit medical histories for all African American clients using the same privacy rules; such rules may differ from those used to collect medical histories from white patients.

Over time, most core criteria become representative of routinized properties. Hence, routinized rules are describe within the CPM context as the types of rules that develop when rule criteria become stable and manifest themselves into routine privacy behaviors (Petronio 2002). These sort of rules can be thought of as pre-established guides that inform and direct the way a discloser will typically go about managing their private information with individuals. With long-term repeated use, routinized rules can become so engrained in an individual's privacy behavior, they function as a concretized orientation, and therefore, difficult to change (Petronio, 2002).

While core criteria address that which is stable, catalyst criteria account for the triggers that lead to rule changes (Petronio & Durham, 2008). Additionally, just as core criteria typify routinized rules, catalyzed criteria are exemplary of what CPM theory refers to as changing rules (Petronio, 2002). CPM theory explains that catalysts are inclusive of factors such as motivational goals, risk-benefit goals, situational conditions, and emotional needs. An individual's motivation can influence him or her to change established rules, such as in the case of a discloser who has a physical attraction to the recipient or if there is the potential to receive some sort of reward as a result of disclosing

(Petronio, 2002). Rule change can be catalyzed when the discloser performs a mental risk/benefit analysis that weighs the advantages of granting access to private information (or the advantages of concealing information) against the degree of vulnerability (Petronio, 2002; Petronio & Durham, 2008). Situational conditions can provoke privacy rule changes such as in the case of a traumatic event, a new life circumstance, or when the discloser engages in a therapeutic session in which openness is an expectation (Petronio, 2002). Lastly, an intense emotional experience, such as rage, passion, or extreme glee, may prompt a disclosure which, in a typical staid emotional state, would remain concealed.

While core and catalyst criteria help describe how privacy rule decisions are made, they are not the only guiding CPM factors for determining the nature of the communication relationship among two (or more) individuals. The next section examines the CPM construct of confidant roles which are varying roles that disclosers and recipients co-create for the recipient. These roles are characterized by the varying expectations and methods by which information is shared and managed.

Confidant roles. Petronio (2002) explains that recipients of private information often take on the role of one of four types of confidants—deliberate confidant, inferential confidant, reluctant confidant, or stakeholder confidant. Role assignment can change based on such things as setting, type of experienced relationship, and the nature of the boundary permeability. Three of these roles—deliberate, stakeholder, and reluctant—are relevant to the current study.

The deliberate confidant is one who receives a disclosure because it has been solicited in the context of providing advice, counsel, or coaching. By nature of their role,

a clinical educator can be perceived by their patients as a deliberate confidant in that they actively solicit private information for coaching and counseling purpose. Petronio (2002) points out though that such a role can lead to dilemmas if there are expectations of reciprocity. This is referred to as the norm for reciprocity which can be understood as a type of quid pro quo, i.e. in exchange for providing a disclosure, one is expected in return (Bradac et al., 1978).

The reluctant confidant is an individual who receives private information, intentionally or inadvertently, but did not have an expectation for such (Petronio, 2002). A passenger on a bus who is disclosed information from a stranger is a reluctant confidant. In this case, privacy boundaries are unwillingly linked as, in most instances, the recipient has no desire to own the information. Petronio (2002) explains though that in some situations, deliberate confidants, who are typically trained to handle disclosures, end up finding out more than they want to know. Thus, a paradoxical situation arises in which the deliberate confidant becomes a reluctant one. In fact, Petronio noted that certain occupations, such as nurses, bartenders, and hair stylists, are predisposed for receiving extraneous or irrelevant information simply due to the nature of their profession. She refers to this subset of reluctant confidants as occupational confidants.

Finally, within the realm of healthcare services, there are those who function as stakeholder confidants. These are individuals such as doctors, nurses, and other patient-facing health professional who, by nature of their healthcare role, receive patients' private health information (Petronio & Sargent, 2011). In other words, a stakeholder confidant is an individual who co-owns an individual's health information because he or she is a stakeholder in the individual's medical care (Petronio & Sargent, 2011). This role

includes an expectation and appreciation for the co-ownership of confidential patient information (Brann & Mattson, 2004).

Stakeholder confidant roles between an HCP and patient are created for two primary purposes. One reason is that patients have an emotional need to disclose to the provider their feelings about their health situation. The other reason is that patients understand that providing private information is a condition for receiving medical and therapeutic care (Petronio & Sargent, 2011).

Street's (2003) ecological model and Petronio's (2003) CPM theory together offer the requisite frameworks for interpreting the current study that explores the nature of the pharmaceutical-sponsored clinical educator role and the challenges posed by the regulatory factors that influence it. The remainder of this chapter summarizes the rationale for this study and the questions that guided its approach.

Research Questions

The scarcity of existing research on pharmaceutical-sponsored clinical educators, along with the complexities of government regulations that impact such services, have revealed a gap in the understanding of the relationship between the patient and a pharmaceutical-sponsored clinical educator. This gap exposes the need for research that explores concepts such as how pharmaceutical-sponsored clinical educators perceive their role, how those educators perceive the impact of their communication with patients, how the educators adapt communication engagements to fit patient or therapeutic needs, how regulatory factors impact the educators' communication with patients, and how educator-patient relationships grow or change over time.

Additionally, as more pharmaceutical companies enlist the assistance of clinical educators for patient education services, and a growing number of patients are utilizing them to receive health information and make healthcare decisions, studies such as this one are necessary for multiple reasons. As noted, there is a relationship between the type and perceived quality of communication patients receive from their healthcare providers and health behavior outcomes, such as adherence rates (Colwell et al., 2005; Lorenzi et al., 2011; Stockl et al., 2010). Similarly, ecological factors can also influence such behavioral outcomes (Fisher et al., 2005; McKenzie et al., 2012; Mudd-Martin et al., 2014; Street, 2003).

This study will help the pharmaceutical industry understand that the regulatory requirements that function as ecological drivers for these programs can influence the programs' adherence goals. Further, the ongoing success of these programs is contingent on knowing how educators effectively and compliantly navigate within those ecological drivers. Additionally, this study can assist the industry by identifying other strengths and weaknesses of the pharmaceutical-sponsored clinical educator model and by providing recommendations to address them. Outcomes from this study can be shared with new and tenured clinical educators through professional development in-services and onboarding programs which, in turn, can lead to improved job performance and fewer compliance violations. Finally, this study is valuable to the policy makers who create the guardrails that regulate these programs. While the primary intent of the regulatory requirements is patient safety, this study will show that, in some instances, their ecological influence may undermine the educational integrity of clinical educator programs. This study will aid in the development or refinement of regulatory policies

that account for their ecological influence while still maintaining requisite safety standards. In order to address these needs and fulfill these goals, the following research questions guided this study:

- RQ 1. What role do ecological factors, such as regulatory requirements, play in pharmaceutical-sponsored clinical educators' communication with patient?
- RQ2: How do those ecological factors influence the way pharmaceutical-sponsored clinical educators establish and manage communication privacy boundaries with patients?

The next chapter will describe the methods that were used to explore these questions.

Chapter 3: Methods

A qualitative approach was selected as the methodology for examining the research questions. Qualitative methodologies for understanding the patient education experience have grown in acceptance by health intervention researchers and are finding their way into publications that have traditionally only printed quantitative studies (Finset, 2008). The rationale for such growth is that qualitative studies in this area are best suited for interpreting the how, why, and what in regard to patient coaching and counseling (Tracy, 2013; Whaley, 2014). Hence, the most appropriate way to address the proposed research questions was through a qualitative approach that provides the educators opportunity to elucidate on their experiences and interpret the meaning they bring to their work.

In this chapter, I will describe the methods I used to conduct this study. I will first describe the recruitment site and provide an explanation of the profession of pharmaceutical-sponsored clinical educator and the duties and expectations of that role. Next, I will explain the sampling methodology used to include defining the inclusion and exclusion criteria as well as describing the sampling rationale and sample size. The participant recruitment and selection process will be reviewed and followed by a summary profile of the participant group. Then, I will describe the data collection process to include an overview of the data sources. Following that description, I will review how the data was analyzed and interpreted. Lastly, I will explain my role in the process and the relationship I had to the phenomenon of study.

Recruitment Site

The participants for this study are pharmaceutical-sponsored clinical educators who provide education and coaching to patients. "Pharmaceutical-sponsored" means the educators work on behalf of a pharmaceutical company, or a patient education services company contracted by a pharmaceutical company, to deliver educational information and support services regarding the company's medication and, in some instances, its indicated disease state. For the purposes of this study, all participants delivered education for medications that needed to be prescribed by a licensed healthcare provider (HCP). In most instances, these educators engaged with patients only after the decision was made by an HCP to prescribe the medication. Additionally, as required by law, these clinical educator services were funded by the companies that manufacture the medication. HCPs are not allowed to bill for these services nor do patients or insurance companies pay for them. Depending on the company, educators can be hired as full or part-time employees or as independent contractors.

The participants for this study were recruited with the assistance of VMS BioMarketing, an Indianapolis-based company who contracts with pharmaceutical companies to deliver patient and healthcare provider education and coaching services through nationwide networks of clinical educators. An individual VMS network is funded by a single medication, typically referred to as a "brand," and consists of a few to hundreds of educators depending on the brand's scope and budget. All VMS patient education networks are for biologic medications that required parenteral administration (i.e. routes other than the alimentary canal) to include self-injection with a syringe or pen/autoinjector device, subcutaneous self-infusion, ambulatory infusion pumps (such as

with insulin), inhalation, or intravenous (IV) infusion or injection in the physician's office or infusion center.

Different VMS networks function in different ways. For instance, most networks use either contractors or employees, though some have used a combination of both. Communication modalities and number of engagements with patients also vary by network. Some networks are structured to be a single face-to-face or group education session, often referred to as a "one-and-done," while others have coupled this initial training with follow-up phone calls. Other networks may be strictly telephonic, or web-conference based, and may include multiple education or coaching calls that extend over numerous weeks or months. For instance, educators for one VMS network engage with patients monthly, either in-person or telephonically, over the course of an entire year. All networks educate the patient on the safety and efficacy of the medication. These types of education sessions are called "branded programs" as the content is guided by the regulatory requirements established by the brand and approved by regulating agencies. All branded program content consists of the medication's indication and efficacy information, safety and side effects profile, and administration instructions. Most branded programs also include information about support services, such as manufacturer co-pay cards and financial assistance programs, syringe disposal programs, and disease-related advocacy or support groups. In addition to branded educational sessions, some networks also offer disease-state and lifestyle education sessions that are referred to as unbranded programs. These programs tend to be offered as a separate engagement from branded programs. Unbranded program content focuses on the nature of the disease itself

as well as disease-related self-management strategies on topics such as diet, physical activity, and mental/emotional well-being.

VMS clinical educators are different than home health nurses. VMS educators are only allowed to *educate* on a product and/or disease-state and *coach* toward self-management skills; they are not allowed to provide medical advice, a term typically meant to encompass any clinical recommendation. Additionally, while some networks allowed for patients to self-inject or self-infuse the medication while the educator is present, educators are prohibited from administering the medication themselves. Educators are only allowed to provide verbal coaching and corrections during the injection or infusion process.

All study participants were clinical educators who were current or former employees or contractors for VMS. Full-time employee educators are salaried and tend to deliver a large and consistent volume of programs on behalf of a specific pharmaceutical client or brand. Conversely, contracted "on demand" educators typically have fulltime employment elsewhere in the field (e.g. physician office, hospital, pharmacy) and provide education services for VMS based on their availability and schedule flexibility throughout the week. These educators are paid on a per program basis and represent most of the total number of VMS clinical educators. Contractors would include those considered "active"—currently assigned and working for a VMS program network—as well as "inactive"—those not currently assigned or working for a program network but able and interested in being deployed should a suitable network become available. Some contracted educators simultaneously serve on multiple VMS brand networks as well as other clinical educator networks not affiliated with VMS.

All participants had a connection to VMS as either an employee or contractor. However, most of the interviewed participants also had additional experiences as a clinical educator hired directly by a pharmaceutical company or by a VMS competitor. These other clinical educator networks tend to be organized and operated in a similar manner as a VMS network. Like VMS, these other networks employ different engagement modalities, such as face-to-face, telephonic, or web-conference, may include more than one engagement or touchpoint with a patient, and may cover disease-state information in addition to product information. Therefore, during interviews and focus groups, participants were asked to reflect on the totality of their experiences as a pharmaceutical-sponsored clinical educator, including experiences working for companies other than VMS.

Sampling

Inclusion and exclusion criteria. Participants were required to have a post-secondary degree in a clinically relevant field such as medicine, nursing, dietetics, pharmacy science, or clinical social work. Participants needed to have provided pharmaceutical-sponsored education services to patients for at least one year, though that time did not have to have been strictly in service as a VMS clinical educator. This was to ensure that the educators possessed sufficient experience to adequately address the interview questions. As the focus of this study was communication between educators and patients, an educator's patient education experience needed to have been through synchronous communication modalities such as face-to-face, telephonic, or two-way web conferencing. Experiences in asynchronous patient education delivery, such as via text messaging, email, one-way broadcast, or online course instruction were permitted

provided they had also included some form of synchronous delivery. Educators needed to be able to describe how their prior experiences of providing direct patient care in the field (e.g. hospital, physician office, clinic) influenced and compared to their role as a pharmaceutical educator. Therefore, they were excluded if they did not have any prior clinical field experience. Lastly, per a request from VMS and approved by the university's Institutional Review Board (IRB), an educator was excluded if he or she was involved in a legal dispute or action related to patient or healthcare provider education with VMS, a pharmaceutical company, a biotech company, or any company who offered similar services as VMS. Participants were asked to verify they were not involved in any such dispute at the start of their interview.

Sampling method. The goal of sampling in qualitative research studies is not to collect a representative sample, but rather to collect a sample of individuals who provide the targeted and pertinent information related to the research question (Grove et al., 2013; Morse, 1994; Sandelowski, 1995). In other words, participants are selected because they all have experienced the phenomenon being studied and are therefore considered to be information-rich. For this project, that shared experience is the delivery of patient education sponsored by a pharmaceutical company.

My intent for this study was to examine the research questions beyond the domain of a specific communication delivery modality, disease state, or employment type. This included understanding the themes and concepts that are present across the breadth of clinical educators and synthesizing those concepts within the constructs of the two theoretical frameworks. Once identified, those concepts can guide future research, such as comparative studies or investigations that examine the experiences of more narrowly

defined clinical educator groups, to see if they held up in those situations. Given the variation of program delivery modalities, disease states, and employment types, I chose a maximum variation sampling strategy. Tracy (2013) defines this as a form of purposeful sampling in which participants represent wide variations of the phenomena under study. For instance, educators from varying combinations of delivery modalities, disease states, and employment types were recruited. Some examples included a telephonic fulltime chronic autoimmune disease educator, a face-to-face fulltime educator for a terminal neurodegenerative condition, and an on-demand (contracted) face-to-face diabetes educator.

Sample size. Unlike quantitative research in which sample size is related to the number of variables measured and determined by a statistical power analysis, the sample size for qualitative studies is less easily defined (Creswell, 2014; Grove et al., 2013). The goal for a qualitative study sample is having enough participants to reach saturation of information—or when no new information is provided and there is repetition of the data (Tracy, 2013). This number can vary from study to study based on the heterogeneity of the participants and the quality of the data provided by them (Grove et al., 2013; Tracy, 2013). The profession of pharmaceutical-sponsored clinical educator consists of a homogenous group of individuals. This was also true of the pool of educators from which participants for this study were recruited. The reason for this homogeneity is that pharmaceutical companies tend to prefer to hire nurses with specialized certifications or credentials and multiple years of experience in the therapeutic area for which they will be providing services. In general, most clinical educators are registered nurses (RNs) who have advanced degrees and/or professional certifications. Most are middle-class white

females in the mid-to-late stage of their career with at least 10 years of experience in the field, and who have primarily worked within the United States. There is heterogeneity, however, in geography and the types of populations they have educated, as well as diversity in disease states and program brands for which they served. Still, many of the drugs these educators represent are targeted to a demographic that includes primarily older patients with common chronic conditions who all face similar barriers and concerns regarding their disease and medications. Therefore, based on the recommendation provided by qualitative methods scholars and the relative homogeneity of the clinical educator population, the sample size goal established prior to starting was 25-30 participants.

Participant Recruitment and Selection Methods

I submitted this study's proposal to the Indiana University (IU) IRB as an exempt review application in November of 2018. Once it was approved a month later, I began recruitment. I was provided an electronic spreadsheet by VMS that listed the names and contact information of all their current and past clinical educators (employee and contracted) segmented by brand network. The networks with the largest number of names were for brands that treated diabetes. In fact, more than two-thirds of all VMS educators had provided education for a diabetes medication. Many educators' names were on multiple lists because they had served on multiple networks. Therefore, I removed duplicates from the list in a systematic manner. If an educator had served on both a diabetes brand network and a non-diabetes brand network, their name was removed from the diabetes brand network list/s. If an educator's name was on two or more non-diabetes brand lists, I kept it on the first brand list in which it appeared and

removed it from all subsequent lists. Similarly, if an educator name was on multiple diabetes brand network lists, it was kept on the first list in which it appeared. This cleaning left two sets of lists, a diabetes brand network set that included 773 unique names and a non-diabetes brand network set that included 354 unique names for a total of 1,127 educators.

I recruited and interviewed participants in two waves. The first wave occurred from December of 2018 through February of 2019 and was followed by the second wave in May and June of 2019. The first recruitment wave included all the names from the non-diabetes brand network set as well as all the male and all the multilingual educators from both sets, a total of 412 individuals. The remaining 715 diabetes-only educators, who were female and delivered education only in English, were recruited and interviewed during the second wave. The reason educators were recruited in this fashion was a strategic effort to help promote the maximum variation of the sample as noted above.

Prior to initial recruitment, I set a sampling goal for securing at least 50-75% of the total number of participants from the first wave of educators because this group was more diverse and supportive of the maximum variation strategy. I achieved this goal with 17 of the 26 interviewed participants coming from the first wave. At that point, I conducted preliminary data analysis which, as explained in the data analysis section of this chapter, led to the support of early sensitizing concepts and the development of initial themes. Then, I explored those concepts and themes further with the more homogenous group of the second wave, as well as during focus groups, to determine if they were substantiated or refuted.

I recruited participants primarily via email. An invitation email was sent out at the beginning of each wave and included a short explanation of the study's purpose and instructions for next steps for those that were interested in learning more (see Appendix A: Recruitment and Participation Communication). All diabetes-only educators and most non-diabetes educators were sent the same initial recruitment email inviting them to participate. However, in order to maximize sample variation, I first sent four customized versions of that recruitment email to small subsets of the non-diabetes educators' set. These four customized emails included a different email subject heading and a modified introductory paragraph that targeted specific clinical educator characteristics. For instance, one email was targeted to the twenty-four fulltime employee educators who represented a brand for the only medication used to treat a non-chronic condition. That network provided education and coaching for patients afflicted with a terminal neurodegenerative disease. Additionally, that network was also unique in that it had the longest timespan of patient/educator intervention; educators would engage with patients monthly over the course of a year, more than twice as long as the next longest network intervention. The email was customized to stress the importance of having the "voice" of those unique educator characteristics represented in the study. That email was successful as seven educators responded, of which four were eventually interviewed.

The second customized email was sent to thirteen current or prior fulltime educators of a network that delivered a series of telephonic-only medication and disease-state education engagements with patients. In addition to the fact that this was one of the few VMS telephonic-only networks that also included multiple engagements with a patient over the course of many months, the educators were unique in that they were

versed in three very different therapeutic areas. This network was for a single medication indicated to treat five chronic autoimmune conditions in the therapeutic specialties of rheumatology, dermatology, and gastroenterology. This email was tailored to emphasize the desire to hear both the voices of telephonic-based educators and those who served a diversity of disease types. Of the seven educators who responded to this initial recruitment email, five were interviewed.

Male clinical educators represented less than four percent of all the educators on the full list, therefore a customized version of the initial recruitment email was distributed to them. That email requested their perspective since their gender made them a minority in their field. Lastly, another minority group of educators, who represented less than six percent of all VMS educators, received a tailored email. That group included educators who provided pharmaceutical-sponsored education to patients in another language in addition to English. The response rate for these last two specialized emails was not as successful as the first two. Only three male educators responded to the customized email with one eventually participating. However, another male educator had responded to one of the earlier specialized emails giving a total of two male participants. Only one individual responded to the multi-lingual educator request, though she did not end up participating. However, a total of three multilingual educators were participants as they had replied to other email solicitations.

After an educator expressed an interest in the study, I responded with two types of follow-up communication. The first was a phone call in which I re-introduced myself, thanked the individual for their interest, and clarified my role as a fellow VMS employee who was conducting the study as part of my requirement for a PhD in Health

Communication at Indiana University Purdue University Indianapolis (IUPUI). The second follow-up communication was an email that contained detailed information about the study along with three attachments (see Appendix A: Recruitment and Participation Communication). One of the three attachments was an IRB-approved Study Information Sheet (SIS). It explained the study's purpose, participation criteria, risks, benefits, confidentiality expectations, and protection measures (See Appendix B: Study Information Sheet). The second attachment was a Letter of Support from VMS BioMarketing that outlined the company's awareness of, and support for, the study (See Appendix C: VMS Letter of Support).

The third attachment was a Participant Information Form (PIF). The purpose of this form was to capture general demographic and professional experience information from prospective participants that would assist me in meeting the maximum variation sampling goal. I used this form as the primary tool for determining whether a respondent was eventually invited to participate. Respondents whose characteristics were identical or similar to those already selected for interviews were declined. The form was published in an editable PDF format that allowed respondents to type information into blank text fields and select clickable check boxes from listed options (See Appendix D: Participant Information Form).

The final tactic I used to help maximize participant variation was snowball sampling. At the end of each one-on-one interview, I asked willing participants to actively encourage their peers to participate in the study. Specifically, I requested that participants reach out and provide my contact information to other educators who they felt would have differing thoughts, attitudes, or perspectives regarding the discussed

topics. This strategy was not successful as only one participant disclosed during her interview that a previously interviewed educator reached out and encouraged her to participate. That same educator had also received a recruitment emails, so she was already familiar with the study.

Participant selection. A total of 142 educators responded to the initial recruitment email invitation and requested additional information about the study. I documented their names, email addresses, phone numbers, brands, and time zones on a participant tracking spreadsheet upon receipt. Of the 142 educators who replied to that invitation and were sent the follow-up communication, thirty-six returned a completed PIF and indicated a continued interest in participating. The remainder either declined to participate or never responded to the follow-up and reminder communications. The PIF for each of the thirty-six positive responses was vetted against the inclusion/exclusion criteria. PIFs were then compared against each other as a means for maximizing variation in the characteristics of disease state, medication administration type, program delivery modality, and employment status. Any educator who desired to participate and was representative of any of the special characteristics noted in the four customized recruitment categories was accepted for interview. This included sixteen of the twenty-six participants, of which, fifteen were selected from the first recruitment wave. I selected the remaining ten participants based on their diversity of demographic factors such as region of the country, age-range, and number of years delivering programs.

Participants

As noted, I achieved maximum variation of the participant group through the use of the PIF that captured both demographic and professional experience information. The

following is a summary profile of the participant group derived from the Participant Characteristics Table, an amalgamation of all PIFs, located in the Appendices.

The group was geographically dispersed with nine from the Midwest, eight from the South, six from the West, and three from the Northeast. Participants were in diverse stages of their career with half in a mid-to-late stage (46-60 age range), five in early-to-mid stage (30-45), and eight in late stage (>60). Educators were nearly evenly divided among those who were VMS employees (thirteen), and those who were contractors (fourteen). One participant had served in both capacities. All but three of the educators were Registered Nurses (RNs). Two were Registered Dietitians (RDs) and one indicated her primary credential as Master's in Health Education. Eleven educators indicated multiple credentials or added a credential, the most common of which was Certified Diabetes Educator (CDE). Twelve educators had been delivering pharmaceutical-sponsored education between three to five years while six had been delivering between six to ten years and eight for more than ten years. All but two educators had experience in delivering face-to-face education either to an individual or a group. Nineteen educators also had experience providing some type of telephonic education while nine had used web conferencing and eight had used texting/instant messaging. All educators had experience providing education for products that were administered via self-injection, although three had not instructed on a self-injection syringe, while another three had not instructed on a self-injection pen/autoinjector. Ten had delivered education for oral medications while nine delivered instruction for self-infused products and twelve taught on products administered in the physician office/infusion center. Diabetes and common chronic autoimmune conditions were the most represented disease types with

fifteen and thirteen educators providing those disease services respectively. Eleven educators trained patients with osteoporosis while six had experience working with those afflicted by neurodegenerative conditions. Four educators were experienced in patient education for hyperlipidemia and five for rare/other diseases. Only one educator provided education services for patients with psychiatric conditions (See Table 1: Participant Characteristics by Pseudonym).

When grouped by recruitment and interview waves, educators from the first wave were a heterogenous group as represented by their demographic characteristics and the type of education programs they provided. For instance, educators from the non-diabetes set represented medications for over thirteen different disease types. In fact, one of the networks in that first wave was for a medication used to treat a terminal condition, the only non-chronic disease represented. Additionally, educators in the non-diabetes set included a mix of both VMS employees and contractors as well as educators who served on networks in which all engagements occurred telephonically or via web-conference. Conversely, the second wave of educators was a homogenous group. In addition to only educating patients who had Type 1 or Type 2 diabetes, these educators were all contractors, all female, and delivered programs only in English. Additionally, while some diabetes networks did include short check-in follow-up phone calls, for the most part, the second set of educators delivered the bulk of their interventions via face-to-face engagements.

Table 1: Participant Characteristics by Pseudonym

	Location*				Age Range			Employment Type**			
	NE	SO	MW	WE	30-45	46-60	>60	CE	FE	AC	IC
Antonia			x				x	x			
Bonnie				x	x			x			
Cora			x			x		x			
Deandra			x			x					x
Evelyn	x					x		x			
Felicia		x				x				x	
Gabi				x			x			x	
Hanna		x				x				x	
Iris	x						x	x			
Janelle			x		x			x			
Karl				x	x			x			
Lois			x			x		x			
Martin		x				x					x
Nadine			x		x			x			
Olivia			x			x		x			
Penny		x			x			x			
Quinn			x			x				x	
Reba				x			x		x		x
Sophie			x			x					x
Tabitha				x			x				x
Ursula		x					x				x
Vivian		x				x					x
Whitney	x					x					x
Xoe				x			x			x	
Yvonne		x					x		x		
Zara		x				x					x
TOTAL	3	8	9	6	5	13	8	11	2	5	9

* Educator's state aligned to one of the four U.S. Census Bureau Regions (2010) of NE: Northeast, SO: South, MW: Midwest, or WE: West

** CE: current employee, FE: former employee, AC: active contractor, IC: inactive contractor

Table 1: Participant Characteristics by Pseudonym (continued)

	Credentials*				Years Educating			Patient Engagement Modality**				
	RN	RD	NP	OT	3-5	6-10	>10	1:1	GRP	TEL	WEB	TEX
Antonia	x				x			x	x	x	x	
Bonnie	x	x		x		x		x	x	x		
Cora	x		x	x		x		x	x	x	x	x
Deandra	x					x		x	x		x	
Evelyn	x					x		x	x	x		
Felicia	x				x			x	x			x
Gabi	x				x			x	x	x		x
Hanna				x	x			x	x	x	x	
Iris	x			x			x	x	x	x	x	x
Janelle	x				x			x	x	x	x	
Karl	x				x			x		x		
Lois	x				x					x		
Martin	x		x	x			x	x	x	x		x
Nadine	x				x					x		
Olivia	x						x	x	x	x	x	
Penny	x				x			x	x	x	x	
Quinn	x					x		x	x	x		x
Reba	x				x			x	x			
Sophie	x			x	x			x	x			
Tabitha	x			x			x	x	x			x
Ursula	x			x			x	x	x	x		
Vivian	x			x			x	x	x			
Whitney	x						x	x	x			
Xoe	x						x	x	x	x	x	x
Yvonne				x		x		x	x	x		
Zara		x		x	x			x	x	x		
TOTAL	23	2	2	11	12	6	8	24	23	19	9	8

* RN: Registered Nurse, RD: Registered Dietitian, NP: Nurse Practitioner, OT: other

**1:1: one-on-one face-to-face, GRP: group face-to-face, TEL: telephonic, WEB: web-conferencing, TEX: texting/instant messaging

Table 1: Participant Characteristics by Pseudonym (continued)

	Medication Administration Route*					Disease Type Experience**						
	ORA	S-IS	S-IP	S-IN	HCP	DIA	CAI	OST	NEU	PSY	HYP	R/OD
Antonia	x	x	x	x	x				x			
Bonnie	x	x	x	x	x	x	x	x				
Cora	x	x	x	x		x	x	x				x
Deandra		x	x	x	x		x					x
Evelyn		x	x		x				x		x	
Felicia			x		x			x				
Gabi		x	x		x		x	x				x
Hanna	x	x	x			x		x				
Iris		x	x				x	x	x			
Janelle		x		x	x		x					x
Karl		x	x				x					
Lois		x					x					
Martin	x	x	x	x	x	x						
Nadine		x	x		x		x					
Olivia		x	x		x		x		x			
Penny			x	x	x	x	x		x	x	x	
Quinn		x	x			x	x	x				x
Reba	x	x	x			x						
Sophie		x	x		x	x						
Tabitha	x	x	x	x		x		x				
Ursula	x	x	x			x	x	x				
Vivian		x	x			x		x				
Whitney			x			x		x				
Xoe	x	x	x	x		x			x		x	
Yvonne	x	x	x			x						
Zara		x	x			x					x	
TOTAL	10	23	23	9	12	15	13	11	6	1	4	5

* ORA: oral, S-IS: self-injected syringe, S-IP: self-injected pen/autoinjector, S-IN: self-infused, HCP: healthcare provider administered

** DIA: diabetes, CAI: chronic autoimmune, OST: osteoporosis, NEU: neurodegenerative, PSY: psychiatric, HYP: hyperlipidemia, R/OD: rare/other diseases

Data Collection

I collected data for this study from four sources. The main data source was single one-on-one interviews with each of the twenty-six participants. A second source was three follow-up focus group interviews with sixteen of the twenty-six interviewed participants. Interviews and focus groups were conducted telephonically since this study was unfunded and participants were geographically dispersed. While the previously described PIF functioned primarily as a recruitment and sampling resource, it also served as a data source. The information from the PIFs was used to customize questions during educator interviews. Additionally, PIF data was included as part of the data analysis and findings related to the first research question. The final data source was the field notes I documented throughout the data collection process. I began collecting data in December of 2018 and continued through August of 2019. The following section describes the interviews, focus groups, and field notes.

Interviews. I conducted a single one-on-one telephonic interview with each participant during the two previously described waves. The first wave of interviews, which included seventeen participants, occurred in January and February of 2019. The remaining nine participants were interviewed as part of the second wave in May and June of that same year. The length of the interviews ran from 45-75 minutes with most lasting approximately one hour. Each interview was scheduled for a mutually-agreed-upon date and time. Scheduling correspondences were done via email and phone. In order to avoid interfering with our regular workday duties, I suggested, and made available, interview timeslots outside the typical workweek hours to include evenings, weekends, and lunch hour breaks. Most interviews took place during one of those timeslots, though I had

flexibility with my own schedule to accommodate interviews from different time zones during workday hours. I documented and tracked all interview dates and times using the electronic participant tracking spreadsheet.

I recorded all interviews with two recording devices. The primary device was a recording app called TapeACallPro that was on my mobile phone. This app recorded and stored a call as an audio file to my personal passcode-protected Google Drive account. Each audio file was then immediately deleted from the Drive account once it was downloaded and stored to my local and backup drives. I also used a handheld digital voice recorder as a backup recording device by engaging the phone's speaker function during each interview. To protect participant confidentiality, I conducted interviews at my home office or in a private room at my company's office. I then removed the irrelevant portions of the conversation from the front end and back end of each audio file before uploading them to my Rev.com transcription service account. Once transcribed, each transcription was corrected for accuracy and had identifiable information removed. The cleaned file was downloaded and a copy imported into the qualitative data analysis software called Quirkos (2019). Each step of this transcription process was documented in the participant tracking spreadsheet.

For the interviews, I used two versions of a semi-structured interview guide, one for each wave (see Appendix E: Interview Guides). The first guide consisted of approximately twenty questions that solicited the bulk of data for each interview. Some questions included additional and optional prompts that were designed to probe for more information, when needed. I made three minor revisions of the first guide early in the interviewing process to adjust for learned insights. These revisions included such things

as rewording questions, changing the order of certain questions, and adding questions related to topics not accounted for during the guide's initial development. While the guide served as a general roadmap, I conducted all interviews using a participant-centered approach that allowed questions to be tailored based on educators' responses. The semi-structured interview guide used during the second wave was similar in format and scope as the first guide. Many of the same questions were included in the second version, though they may have been modified or reworded to account for learnings from the first wave. The main difference in the second version was the inclusion of additional questions written specifically to address sensitizing concepts and ideas that were emerging from the preliminary data analysis that occurred between the two interview waves.

Focus groups. I conducted focus groups with educators as a form of member checking—a process by which emerging themes and ideas were validated or refuted by those who participated in the interviews (Creswell, 2014). These focus groups occurred in August of 2019 after the completion of all one-on-one interviews and following a portion of the data analysis process that led to the development of preliminary themes. I invited educators via email to attend one of three telephonic focus groups sessions (See Appendix A: Recruitment and Participation Communication). Each email invitation was sent individually as it informed the educator of their pseudonym, which they were requested to use during the focus group discussion. A copy of the Study Information Sheet (SIS) was attached to the email to remind participants of the purpose, benefits, and risks of the study.

Sixteen of the twenty-six educators participated in a focus group; seven in the first group, four in the second group, and five in the third group. I placed educators in a specific focus group based on their availability and to create as equal-sized groups as possible. Educators who did not respond to the initial focus group email invitation were sent a reminder email a week later. Reasons for non-participation included unavailability for any of the three dates, lack of response to the focus group invitations, and no-show/forgetting to attend. All focus group correspondences, responses, and educator availability dates were documented in the participant tracking spreadsheet. Each of the three focus groups were scheduled to last one hour.

A few days prior to their focus group, participants were emailed a telephonic dial-in number. I used VMS' audio bridging service called Zoom to connect all participants in a multipoint call format. All participants could speak freely at any point of time during the focus group and each participant could hear one another. Along with the dial-in number, I also included in the email a focus group discussion guide (see Appendix F: Focus Group Discussion Guide). This was done in advance to give the educators time to review the guide's content and to prepare themselves for the discussion. Educators were encouraged to have the guide accessible during the meeting. The content of the guide included an abstract of the study, the two research questions, a brief review of the one-on-one interview process, a summary of participants and their characteristics, a brief explanation of the two guiding theories, and a list of seven preliminary themes that were emerging from the interview data. Each theme included two to four bulleted sub-themes listed below it. I also included discussion questions for four of the themes that were of greatest interest at that point in the data analysis process.

I provided explanations of the two study theories, the ecological model of communication in the medical encounter and communication privacy management (CPM) theory, in the discussion guide for two reasons. First, the explanations helped provide background for some of the preliminary themes and sub-themes. Secondly, most educators were clinicians with advanced degrees and certifications who had training and experiences in both the theoretical and practical tenets of patient-provider communication. Therefore, asking educators to reflect on the themes, in the context of those theories, and engage in relevant conversation, was not beyond the scope of their capabilities.

During the focus groups, I facilitated the discussion using the themes as conversational prompts. To accommodate the limitation of only having an hour for each call, I focused first on themes in which I found a diversity of responses in interview transcripts or those that were requiring more in-depth clarification and supporting data. These were the themes that included discussion questions printed in the guide. Themes that had little disparity of responses or that were sufficiently supported by existing interview data were discussed toward the end of the meeting when time allowed for it. All three focus groups were recorded, transcribed, and checked for accuracy and confidentiality using the same services, tools, and protocols outlined in the one-on-one interviews.

Field notes. In addition to the participant tracking spreadsheet, I kept field notes throughout the data collection process. The most extensive notes were those that followed each one-on-one interview. Shortly after the completion of an interview, I documented my personal reflections of the event to include such components as

summations and highlights of what was discussed, insights related to the interview process and educator responses, a self-assessment of my interviewing acumen and suggestions for improvement, potential changes to the interview guide, topics or concepts for further defining or additional exploration, and emotions that were prevalent during the discussion. I then reviewed each interview's notes immediately prior to the initial coding of the interview transcript and then later throughout the data analysis process. In addition to the interview field notes, I also documented ideas and reflections during the early stages of the data analysis process prior to the second wave of interviews. These notes outlined emerging concepts and ideas with sample quotes to support them, discrepancies in the data, and ideas for how to explore new topics in the second wave of interviews.

The next section explains the constant comparative approach that was employed for data analysis. This is a methodology in which analysis occurs in iterative stages with frequent revisits to guiding theories (Glaser & Strauss, 2009).

Data Analysis

Data analysis was an iterative process that started while data were being collected in early 2019 and continued through the fall of that same year. For the purposes of this study, Tracy's (2013) conception of "iterative analysis" best represents the methods by which I examined and made sense of the data. Tracy explains this term as the way in which analysis continuously alternates between emergent readings of the data and active reflections of existing models and theories. The constant revisiting of theories while immersed in the data enabled me to progressively refine emerging themes while expanding the knowledge gleaned from them (Tracy, 2013). For instance, though structured first-level coding of data for this study did not begin until completion of the

first wave of seventeen interviews, I engaged in unstructured iterative analysis as early as completion of the first few interviews. As described previously, I adjusted the interview guide during the first wave based on insights gained shortly after completing a handful of interviews. The purpose of those adjustments was to promote a more focused exploration of the theoretical tenets and relevant "lenses"—or what Tracy referred to as sensitizing concepts—that were guiding the study.

Sensitizing concepts. Qualitative scholars have described sensitizing concepts as interpretive devices that serve as starting points or lenses for guiding inquiry (Charmaz, 2014; Tracy, 2013). Charmaz (2014) goes on to explain how a qualitative researcher will frequently begin with existing empirical interests and a loose framework for how they will look at them. Those interests initiate the sensitizing concepts that serve as points of departure for forming interview questions, listening to interviews, and analyzing data. In the context of this study, one example of a sensitizing concept was the construct of dual loyalties, the notion that clinical educators felt a sense of obligation to both the patients they educated and the pharmaceutical company that sponsored them. As is often the case in a client-employee-employer relationship, the needs the employee is expected to fulfill for the betterment of the client may conflict with the needs the employee is expected to fulfill for the betterment of the employer. As I approached this study, I believed that this notion served as the crux for how and why regulatory drivers such as on-label compliance, fair-balance presentation, and adverse event reporting created tension in the interpersonal communication that occurs between the educator and the patient. Educators must constantly make communication decisions that weigh the value of the outcome of the patient against the value of the outcome for the pharmaceutical company. During

data collection, my role was to ask the type of questions and listen for the types of answers that explored the inherent tension at the heart of that sensitizing concept. Then, during the early stages of the iterative analysis process, I identified parts of the data that supported or rejected the sensitizing concepts in the context of the two guiding theories. When necessary, questions for second-wave interviews were adjusted to account for data discrepancies regarding the concepts. Finally, during late stage iterative analysis, those concepts were either accepted or modified to fit within the primary assertions of the theoretical model or were rejected outright.

The next section describes the beginning stages of this iterative data analysis, a process called first-level coding (Tracy, 2013). It is during this phase that descriptive terms, or codes, were applied to interview transcripts. These codes were then mapped to new concepts or to those sensitizing concepts that have been previously derived from the two theoretical frameworks.

First-level coding. First-level coding, or descriptive coding, was the first form of structured qualitative analysis that I conducted. This is a type of coding in which descriptive words or phrases are assigned to recurring ideas or concepts identified in the transcript data (Tracy, 2013). First-level coding began in April of 2019 after all seventeen first-wave interviews were transcribed and checked for accuracy. I created an electronic codebook in a spreadsheet to document first-level codes to include each code's abbreviated short-form name, the full long-form name, and a definition. The spreadsheet also included a column that cross-referenced each code to similar or related codes (See Appendix G: Codebook). Definitions and cross-referenced codes were useful because they allowed me greater efficiency when coding sections of transcripts.

Initially, I coded transcripts manually in the order in which the interviews occurred. I read a printed version of the transcript and wrote in the margin a term or phrase that captured the essence of a sentence, phrase, or short passage. That short-form version of the term was then documented on a notepad. I continued this process by adding or editing codes for each new concept as it appeared. Upon completion, I entered the handwritten list of codes into the spreadsheet where it was alphabetized, translated to long-form terms, defined, and cross-referenced to related codes. The first interview transcript generated approximately sixty first-level codes. This procedure was duplicated with the second transcript during which the codebook was used to refer to existing codes while new codes were handwritten on the notepad. I then added the new codes into the codebook spreadsheet, defined them, and cross-referenced them. This process continued until new codes were exhausted by the fifth interview. At that point, I had generated a total of 169 first-level codes. I continued coding six more interviews with first-level codes. By the eleventh interview, I understood the patterns that were emerging and recognized how frequently coded terms were starting to group together in the framework of sensitizing concepts related to the guiding theories. At this point, second-level coding could begin.

Second-level coding. This level of coding is the organization, synthesis, and categorization of first-level codes into interpretive concepts (Tracy, 2013). Many of the second-level codes were representative of, or akin to, sensitizing concepts that were derived from the two theoretical frameworks prior to beginning or that emerged during data analysis. For the purpose of this study, I grouped all second-level codes within a parent group category. These groupings were organized by primary constructs of the

guiding theories or as sensitizing concepts that shared a common theme (See Appendix G: Codebook). Most of the parent group categories served as a precursor to a preliminary theme developed during the latter stages of data analysis. An example of a parent group that was organized by the sensitizing concepts from a guiding theory was the one titled "CPM Confidant Roles to Patients." It was inclusive of secondary-level codes that represented three types of confidant roles noted in the communication privacy management theory (Petronio, 2002). Those codes were "RolePTDelib" (deliberate), "RolePTReluct" (reluctant), and "RolePTStake" (stakeholder). Each was coded to transcription data that exemplified a clinical educator's interpretation of a patient relating to, or interacting with, them as a deliberate, reluctant, or stakeholder confidant. An example of a parent group organized by sensitizing concepts that shared a common theme was the group titled "Dual Loyalty." It was inclusive of second-level codes that represented a type of dual loyalty dilemma experienced by educators. This group consisted of the secondary level codes "DLPtVPharm" (dual loyalty—patient vs. pharma), "DLPtVHcp" (dual loyalty—patient vs. healthcare provider), and "DLPtVFam" (dual loyalty—patient vs. family). Each was coded to transcription data that exemplified a clinical educator's interpretation of a sense of conflicting loyalty between their patient and an "other" (i.e. pharmaceutical company, HCP, or family member).

I began the next phase of data analysis by creating a list of second-level codes on a notepad while referencing the list of first-level codes. Some first-level codes migrated to second-level codes as supporting data revealed them to be representative of larger interpretive concepts. I entered all second-level codes in a separate tab in the codebook spreadsheet, assigned a short-form name, and defined. Codes were organized and

assigned to parent groups which were also defined. I approached the coding process for this level in a similar fashion to first-level coding, starting with Interview A, and using printed transcripts while handwriting codes in the margins. Because some first-level descriptive codes were indicative of the larger second-level interpretive concepts, I frequently referred to the first-level coded transcripts to assist in assessing transcript data and assigning second-level codes. Additionally, I also frequently referred to code definitions to ensure consistency. As the first few transcripts were reviewed, I made edits and additions to the second-level codebook to account for concepts not identified in the initial version. By the third interview, all second-level codes were solidified to include fifty-nine unique codes organized within fourteen parent groups.

I performed second-level coding with eight of the seventeen first-wave interviews by hand. At that point, I felt comfortable with the process and migrated to coding using the Quirkos (2019) qualitative data analysis software. Once I imported each electronic transcript (Interviews A through Q) into the software, I dragged and dropped selected portions of text data into the hierarchical code fields. I created parent group and second-level code fields within the software that mimicked those developed in the codebook spreadsheet. The eight hand-coded transcripts were migrated first and recoded into the electronic fields using the handwritten margin codes as a guide. The remaining nine transcripts were coded directly in the software.

The second wave of nine interviews (Interviews R through Z) took place at the same time as the electronic coding of first-wave transcripts. Those interviews used the revised interview guide that included new questions related to second-level interpretive concepts such as the various types of dual loyalty ethical dilemmas. Once those

interviews were completed, they were electronically coded using the same second-level code fields as the first wave. Lastly, focus group transcripts were electronically coded shortly after those events occurred using the same process as the interview transcripts.

Throughout the second-level coding process, I copied sentences and passages of transcript data that stood out as exemplary representations of second-level interpretive concepts to a separate tab in the codebook spreadsheet. Such passages were referenced as quotes during the construction of the Findings and Discussion chapters.

The qualitative software contained other functions that allowed me to manipulate and manage the transcript data in ways that assisted in the latter steps of analysis. For instance, I was able to click on each individual code field to view all the text segments across transcripts that were assigned to that code. This was a useful tool for selecting the most relevant or salient examples for inclusion in the Findings and Discussion chapters. This function also helped me organize the structure and layout of the core components of each theme as it was developed. That process, called thematic development, was the last step in data analysis.

Thematic development. The *a priori* sensitizing concepts, along with the field notes and new interpretative concepts that were revealed as part of the second-level coding of data, began to evolve into themes that guided the explanation of the Findings and subsequent Discussion chapters. I began documenting preliminary themes following second-level coding of interview transcripts and prior to the focus group meetings. Those themes were included in the focus group discussion guide sent to educators and served as catalysts for discussion. Each theme contained component sub-themes that further defined and explained the main assertion of the parent theme. One example was a

preliminary theme related to the ecological model of communication (Street, 2003) that emerged from the data but was not an a priori sensitizing concept. That theme was defined in the discussion guide as, "A context, not previously identified in the ecological model literature, emerged from the interviews as having significant influence in the conversation dynamics between the educator and patient. This is the disease context." One of the sub-themes for that theme stated, "The types of factors educators identified that could fit within a disease context include chronic or terminal prognosis, disease side effects, treatment side effects, pregnancy status, drug administration modality, prevalence of disability or comorbidity, and where the patient was on their disease journey." This theme was affirmed during the focus group discussion and continued to be supported by on-going data synthesis. Therefore, I included a revised version of it as part of the Chapter 4 Findings. However, I also added, deleted, or refined other sub-themes, or components of sub-themes, to align with a deeper analysis of the data and guiding theory. For instance, I determined the segment of the sub-theme that states "…and where the patient was on their disease journey" was not a component of the newly identified disease context. Rather, upon reflection, the concept of a "disease journey" had already been accounted for in the literature as part of Street's ecological model.

Other preliminary themes noted in the discussion guide went through a similar process of constant comparative analysis to the data collected in later stages of the study with reflection back to the guiding theoretical frameworks. Most of the preliminary themes were affirmed and carried through, albeit with similar revision and refinement, to the Findings chapters. A few themes were rejected outright or underwent significant change, not because the preliminary versions were erroneous in their assertions, but

rather they were not in full alignment with the current research questions. Those themes could serve as starting points for research questions of future studies that utilize this data or other sets of data related to the pharmaceutical-sponsored clinical educator experience.

The final section of this chapter examines the unique relationship of my role as a researcher to the phenomenon of study. Further, it describes how that affiliation influenced my interpretation of the Findings.

Researcher Role

My role in this study was that of the "participant observer." In that regard, my experiences, reflections, and interpretations influenced the data collection and analysis process due to my immersion with the participants and the data collected from them (Grove et al., 2013). Additionally, my relationship to the study topic and to study participants was different than most research projects in that I worked with the participants being researched. Hence, I could bring a unique perspective to the studied phenomenon. Some of those insights were brought forth in the Discussion chapter. Tracy (2013) explained how the participant observer role is analogous to Victor Turner's concept of liminality—the notion that "people are neither here nor there; they are betwixt and between the positions assigned and arrayed by law, custom, convention, and ceremony" (p.76). In other words, a participant observer must be close enough to the studied population to understand them, yet simultaneously far enough away to maintain an outsider perspective. My role and experiences at VMS had afforded me the necessary closeness to understand the participants and the phenomenon of interest. However, there were also two ways in which I was able to mitigate influence of my VMS role during data collection and analysis.

Though I was studying clinical educators, I had never served in that role. Therefore, I was an outsider to the group having never had a shared experience. Additionally, except for a small number of direct observations previously completed as part of an internal auditing process, my understanding of the pharmaceutical-sponsored clinical educator experience was mostly based on anecdotal data along with some limited insights gleaned from the few studies that are in the literature. The anecdotal data included information garnered from my interactions with educators when they periodically visited the corporate office or from my daily casual conversations with VMS office staff members who worked closely with the educators and managed their networks. While my role as a clinical educator trainer did frequently allow interaction with the educators, most of those engagements typically occurred as part of their new-hire onboarding, prior to the delivery of programs. There was no regular on-going contact with educators once they were trained and released to the field.

Secondly, I addressed the potential influence of my role through the data analysis methodology. This included the member checking strategy during which participants were asked to review, reflect on, and provide confirmation of findings. Such a process can occur at any stage, but frequently happens during later stages of analysis following the emergence of themes and assertions (Charmaz, 2014). Additionally, as Creswell (2014) explains, member checking is a suitable device for helping ensure a study's qualitative validity and reliability—or the degree by which the findings are deemed trustworthy, authentic and credible.

The next two chapters explore the final themes, and their component sub-themes, that emerged from the completion of the data analysis. Each theme is supportive of one

of the two research questions. Chapter 4 Findings examines those themes that align to the first research question which focuses on Street's (2003) ecological model of communication in the medical encounter. That question states, "How do ecological factors, such as regulatory requirements, function within pharmaceutical-sponsored clinical educators' communication with patients?" Chapter 5 Findings looks at those themes supportive of the second research question. That question narrows how some of those ecological factors act within the context of Petronio's (2002) communication privacy management theory. That question states, "How do those ecological factors influence the way pharmaceutical-sponsored clinical educators establish and manage communication privacy boundaries with patients?"

Chapter 4: Findings—Ecological Model of Communication in Medical Encounters

The findings for this chapter are examined within the context of Street's (2003) ecological model of communication in medical encounters and address the first research question: *"What role do ecological factors, such as regulatory requirements, play in pharmaceutical-sponsored clinical educators' communication with patient?"* Street's model posits that ecological factors influence the nature and scope of interpersonal patient-provider dialogue in medical encounters. These factors are segmented into four socio-political and demographic contexts, as well as one interpersonal context, that impact both the patient and the healthcare provider (HCP) and the way their interactions unfold. For instance, the *cultural context* is comprised of factors such as race, gender, ethnicity, religion, geography, education, and socioeconomic status. The *media context* includes factors such mass media exposure as well as access to and use of the Internet and telemedicine. The *organizational context* includes the influence of structures such as managed care, available medical services, and the standards of care that drive those services. The *political/legal context* includes factors that are tied to governments' influence such as the Affordable Care Act (ACA), the Health Insurance Portability and Accountability Act (HIPAA), and government-funded healthcare programs like Medicare and Medicaid. While these four contexts are representative of the external factors that impact communication, Street also explains that there are internal forces of influences that comprise the *interpersonal context*. This context is divided into cognitive/affective influences, which are factors that incorporate an individual's goals, perceptions, and emotions, as well as predispositional influences, which are factors related to communication style, individual self-concepts, and access to linguistic resources. Lastly,

Head and Bute (2017) identified an additional context, *everyday talk*, to account for the influence of conversations that occur outside the medical encounter, such as with family and friends, that later impacts patient-provider communication.

Data from the interviews revealed that factors from all five contexts influenced the communication dynamics between the clinical educators and their patients. However, for the purposes of this study, only Street's fourth context, the political/legal, is applied in these findings. The rationale for focusing on this context is four-fold and includes: (a) educators described how the factors from this context influence the way they communicated with patients, whereas for the other three contexts, educators tended to focus on the reverse dynamic (i.e. the way those factors influenced how patients communicated with them), (b) most of the insights educators provided regarding the other four contexts reinforced and supported known assertions and findings from prior studies related to this model, (c) the regulatory environment in which these factors operated made this context particularly relevant, and (d) the richness of the data related to this context was the most appropriate for addressing the research question.

While only one of Street's and Head and Bute's five contexts is explored here, a new context emerged in the data. This context, the disease and treatment context, potentially reveals a wealth of insights related to how disease and treatment-related ecological factors influenced the communication dynamic between the clinical educators and their patients. The interviews highlighted that a range of communication challenges arose from the disease and treatment context, as well as the political/legal context, which in turn, created barriers that impeded patient self-management behaviors. Educators,

therefore, provided insights into the many types of verbal and nonverbal strategies they employed to help navigate patients through those challenges.

This chapter is organized around four themes that represent the major findings as related to the ecological model and the first research question. Those themes are:

1. Political/legal contexts factors, manifested in pharmaceutical industries' compliance regulations, greatly influenced clinical educators' communication with patients.
2. The influence of ecological factors, particularly within the political/legal context, would frequently force educators to experience ethical dilemmas.
3. A sixth context, the disease and treatment context, not previously identified in the ecological model literature, emerged from the interviews as having significant influence in the conversation dynamics between the educator and patient.
4. Educators employed communication strategies to better navigate within the political/legal and disease and treatment context ecological factors.

Compliance Regulations in the Political/Legal Context

Theme 1. Political/legal contexts factors, manifested in pharmaceutical industries' compliance regulations, greatly influenced clinical educators' communication with patients.

When educators discussed factors related to a political/legal context, specifically industry and government mandated compliance regulations, they expressed in broad and varied opinions how those factors impacted the way they communicated with patients. This theme explores those discussions starting first with educators' beliefs about the necessity of the regulations for protecting their patients' well-being and mitigating their employers' liability. Here, educators explained how they understood the intense legal

pressure their companies constantly faced; however, they also expressed disappointment with how liability seemed to be prioritized above all other things. Next, the educators' criticisms toward compliance regulations are examined, specifically their views regarding the influence of the three regulatory factors of fair-balance presentation, staying on-label, and adverse event reporting. It is here that educators shared their frustration with the regulations as factors that would often stifle communication and inhibit patients' comprehension of information. Lastly, as a result of their frustrations and beliefs that some compliance regulations were counterproductive, educators admitted to engaging in purposeful non-compliant communication behaviors.

Compliance necessity. When educators spoke about the necessity for compliance measures, they would typically frame their beliefs in a pragmatic context, such as the regulations offered guidance that prevented errors and provided protection. Felicia, a registered nurse (RN) and educator for an osteoporosis medication said, "It's a plan to follow…So you never have a patient that says, '[Felicia] said I could do that.' And then the doctor tells the [sales] rep and the rep is like, 'I can't believe she did that kind of thing.'" Ursula, an RN and a diabetes and osteoporosis educator, thought the regulations were important for those who see themselves as rule-followers, "I think they make it easier, because they're expectations that you're...This is what you should do. And I'm kind of a rule follower, so it was nice to have that very clear definition of this is what you do." A similar sentiment was offered by Evelyn, an RN who had experience educating patients with neurodegenerative conditions. She even went as far as to imagine government regulators as part of every program she delivered when she stated, "I'm a

rule follower. I just always pretended that the FDA was somebody that I was teaching or they were in the room."

Hanna, a dietitian and educator for both diabetes and osteoporosis products, appreciated how compliance regulations gave her succinctness and little room for error. She stated, "Because the expectations are already set. What you can do, what you can say is all very concise. There is no gray area to it." She also credited her prior experience as a pharmaceutical sales representative as creating a compliance-oriented mindset, "Well, I think it's probably easier for somebody who has come out of a pharma sales position to understand all of that than it is probably maybe for someone who has not had that experience." Penny, an RN who also had prior experience as a pharmaceutical sales rep echoed the protection-related language while simultaneously highlighting that regulations can create limits, "It definitely limits modes and ways of clinical education, but they exist for a reason, to protect everyone."

Finally, there were some educators who simply understood the regulations to be part of their job and a valid expectation of their employer. Therefore, whether they agreed with the regulations was irrelevant. Martin, a nurse practitioner and certified diabetes educator (CDE) summarized it this way, "It doesn't matter what I think should be done. I'm there representing the company. They have told me how they want it done. And it's my responsibility to deliver the message like they want it delivered."

Compliance and liability. Educators recognized that adhering to compliance regulations was more than just an expectation of the companies that employed them. Most understood the high degree of scrutiny and vigilance the industry faces from government agencies. Tabitha, an RN and CDE who has worked with many diabetes

drug manufacturers stated, “The pharma companies are so highly regulated, and the government will go after them like vipers if it’s perceived that they’re not toeing the line.” Educators also recognized that non-compliance offenses can lead to costly fines or multimillion-dollar court settlements against pharmaceutical companies by state and federal governments. Penny, an RN and former pharmaceutical sales rep who also has provided education for multiple disease types, shared, “…because liability wise, one slip costs millions and millions of dollars and billions of dollars too. So that’s why [compliance regulations] exist.”

While many of the large lawsuits against the industry have focused on the behaviors of the companies’ sales representatives and marketing team (Harris, 2009; U.S. Department of Justice, 2013), a few educators were aware that federal investigations have been launched against the companies because of their patient support programs (PSPs) (Loftus, 2018). These court cases accused educators of functioning as a type of “white coat marketing”, an industry term that describes the use of healthcare professionals for marketing products to patients. Deandra, an RN who has trained patients on products for autoimmune conditions, stated during her focus group, “There have been some recent lawsuits going on with the pharma educators. Department of Justice is claiming that educators are really just doing whitewashed selling or white coat selling. That they’re not really educating.” During her focus group, Tabitha shared her realization that she may have unknowingly served as a white coat marketer because her program was in violation of parts of the Sunshine Act. This federal legislation, which is part of the Affordable Care Act, seeks to track and control payments and “items of value” provided to HCPs by pharmaceutical companies (Richardson, 2014). In some of their court cases against the

companies, the government has interpreted items of value to include clinical educators (Loftus, 2018). As Tabitha explained, "The doctors were thrilled and once they realize this was a great deal, they continued to write prescriptions for [pharmaceutical company] insulin, which I guess is what put an end to this entire program…this was considered some sort of bribery."

For many of the educators, liability concerns directly influence how and what they say to the point they warned patients of the regulations' impact. Deandra shared, "I always say to my patients, not only do we practice medicine, but we practice law. There are certain things you had to be careful in how you respond because legally, you could be stepping in some hot water." Gabi, an RN with pharmaceutical education experience in multiple therapeutic areas, implied that the constant compliance vigilance pushed by some companies caused her to feel paranoid. She said, "There's one pharmaceutical company that seems to be so concerned...very litigiously minded and to the point where we feel like I just say the wrong thing and the FDA is going to show up at the door." Antonia, an educator who engages with patients on a monthly basis, reflected on how liability concerns limited her ability to document information about her patients, "In this job, data entry, most companies are afraid of being sued, so you're not really allowed to enter much. Just that I was there."

Educators lamented that the focus on liability protection had made them question the pharmaceutical companies' commitment to proper and authentic patient education. Lois, a telephonic educator for a drug used to treat multiple indications, summarized it this way, "I think that they're so tied down by legal matters and legal...the legalities of everything, that I don't know that [patient education] is that important to them, honestly."

Reba, an RN and diabetes educator, went as far as to question the legitimacy of the industry's liability concerns because they were counterintuitive to the goals and purpose of patient education. She said, "I never truly understood the comments that they made about having to meet all these federal regulations for exactly what you're going to say. To me, that's not education. Education isn't forcing something down a patient's throat." A similar sentiment was offered by Iris, who provided education for patients with chronic autoimmune diseases, when she stated "…you always have to think around the issue so that you can remain an advocate to your patient because a lot of the regulations, they're legal and they're made by people who really don't understand patient interaction at all."

Educators frequently expressed that the companies' intense focus on liability concerns constrained their ability to properly deliver a program. Antonia explained, "I feel like the pharmaceutical company we work for are compliance maniacs. I don't know, I could be wrong about that. But we have so many restrictions regarding compliance it's hard sometimes to do our job." Lois, a telephonic educator for a drug used to treat autoimmune conditions similarly complained, "You always have to have in the back of your mind the rules and restrictions that you need to follow when you're talking. So, you just can't be as free in your conversation as you would like to be." Gabi, an RN and former pharmaceutical sales representative, believed that the strict focus on compliance by some companies took away from the naturalness or authenticity of the patient-provider experience. She stated, "There's this one company that's to the point where you're afraid to say anything. It makes if difficult because you're so concerned that you might say the wrong thing instead of being natural...it impedes our care for the patient."

Reba, an RN and diabetes educator, echoed a similar notion as she compared the pharmaceutical role to her previous responsibilities working in the field, "You're always looking at maintaining and following all the rules and regulations. Sometimes you don't say as much or go into as much detail as you would in say my work setting where I didn't have to worry about that." Sophie, another diabetes educator, also appreciated how her field roles provided her more autonomy to adapt educational materials as she felt necessary. She explained,

> So, the differences in the hospital, for me, are much more elaborate on how I would explain something to the patient. I'd draw things out for them…whatever angle I need to change my words up, maybe to have them understand it. I had a lot more flexibility in the hospital and autonomy than doing pharmaceutical programs. Like I said, it was really strict…just present what was on the flip chart. So, you really couldn't draw anything different. Everything had to be pharmaceutical approved…So I felt it was very, it was stringent, everyone doesn't learn that same way.

Many of the liability reduction measures that provoked educators' feelings of restrictiveness were outgrowths of the industries' response to the government-mandated regulations created to protect the public. Three of these regulations drove compliance policies and served as factors that were the object of educators' ire. The next section examines these three political/legal factors and their influences on the educator/patient communication dyad. These factors contributed to most of the criticism educators had regarding compliance regulations.

Compliance factors that influenced communication. Educators highlighted three government and industry mandated compliance policies that were foundational to the way they engaged with patients. These influencing factors not only drove *how* they spoke with patients, they also dictated much of *what* they could say as well as how they could respond to patients' questions and concerns. The factors of fair-balance presentation, staying on-label, and adverse event reporting are policies mandated by the government and enforced by the industry to help protect the consumers of prescription medications. While educators understood the rationale for such protective measures, and even supported their necessity, they also bore the brunt of many of their unintended consequences.

Fair-balance presentation. Fair-balance presentation is an industry guideline that requires an equal balance of product benefits with product risks as part of any promotional activity (U.S. Food & Drug Administration, 2015). Deandra, an RN and educator for autoimmune disease products, had a more whimsical interpretation. When asked what the term meant to her, she replied, "You give them the good, the bad, and the ugly." Yvonne, a diabetes educator, used the same euphemism while clarifying the necessity of fair-balance presentation. She shared, "I'm going to tell them the good, the bad, and the ugly…I just want them to make an informed decision, because like I said, I go home at the end of the day. [The patients] do too." Part of the "ugly" that Yvonne referred to would include the requirement to discuss "black box warnings". These are warning instructions that are enclosed in a black box on the printed prescribing information of drugs that pose special problems, such as that those that might lead to death or serious injury (U.S. Food & Drug Administration, 2015). She described it this

way, “If it’s got a black box warning, you’ve got to say it and you’ve got to say it the way the FDA wants it said. If it scares the patient, I’m sorry. It’s still there. You’ve got to tell them.”

One way pharmaceutical companies help ensure fair-balance presentation in clinical educator programs is by using program scripts, instructional guides, and pre-produced educational materials. Bonnie, an educator who delivered programs for many different products and therapeutic areas, explained their rationale this way, “Again, it’s just so critical that we maintain that everyone’s saying the same thing, that it’s what’s approved, that it’s accurate information.” While Bonnie was correct that all materials and scripts contained the approved and accurate information to which educators were to follow, the complexities of the scripts varied from network to network. Some networks’ program materials and scripts contained near-verbatim language to which educators were expected to follow. Other networks preferred to give the educators more leeway by providing talking points instead of exact verbiage, though the expectation was still that educators not deviate from the key concepts or “spirit” of the message. Vivian, an RN and diabetes and osteoporosis educator described it this way, “Some of the programs were extremely scripted. You could only say what was on the board and on the flip chart. You couldn’t elaborate, couldn’t answer a lot of questions. Others were a little more liberal and you could elaborate.” Cora, a nurse practitioner who provided product education programs for diabetes and autoimmune conditions had a similar interpretation, “It will vary from one company to the next. Some will just give discussion topics and then you’re allowed to have more liberty and freedom. And then other companies really don’t want to leave anything up to chance.”

Script restrictiveness was viewed as troublesome by educators as it impeded proper assessment of the patient. Vivian felt this was especially problematic for those patients who were newly diagnosed or who had little understanding of their disease. She lamented, "It makes it difficult to stay on a scripted program when you know the patient has never heard a word about diabetes…to find where your patient's at, if you don't have that wiggle room, to get that assessment part in." Interestingly, Bonnie noted that the inflexibility of scripted programs could be equally detrimental to well-informed patients when she stated, "If a patient has done their own research…they may have their hopes up that they're going to get more information or more personalized information, and then they may be disappointed because of those standards and that compliance." Penny, an educator for patients with neurodegenerative and autoimmune conditions, explained that because scripted programs tended to create an unnatural presentation style, they could be off-putting to the point patients would stop participating. She stated, "I think when clients or patients are in an overly robotic consultation or discussion, they're more likely to opt out of the services." Similarly, the expectation to never deviate from the script frustrated educators. Sylvia admitted it was the reason she stopped delivering programs. She shared, "I think that was what ultimately led to me stopping doing the programs, because it wasn't fun anymore…it had gotten to the point that if it wasn't on the paper, you couldn't open your mouth and say anything about it."

Educators who delivered their programs over the phone shared many of the same arguments against highly scripted materials, though they also pointed out some concerns that were unique to their program delivery modality. For instance, Cora, a telephonic educator who supported medications for multiple diseases, noted that the inability to see

her patients exacerbated the weaknesses of scripted programs. She explained, "It's a little challenging when you're so scripted and you're on the telephone. That's a little more challenging too versus when you're doing webinars where people can see you on camera and you can do a little bit more explaining." Another expectation that seemed to frustrate telephonic educators was some companies' requirement to read verbatim the Important Safety Information (ISI) at the end of the program or even every time the drug name is mentioned. The ISI a summary of a drug's risks that the Food and Drug Administration (FDA) requires to be included within every promotional artifact or presentation (O'Donoghue et al., 2014). Lois explained, "And then part of the script is reading the Important Safety Information message that is a requirement if the name of drug is mentioned…it was a huge adjustment, coming from where I didn't even have to worry about that." Bonnie provided further clarification by noting how the ISI was a redundant document that, by reading verbatim, added a lot of unnecessary time to the call. She stated, "Sometimes it's time consuming or we're keeping someone on the phone who's already been on the line for a long time so that we can read them another five or seven minutes of information that they have access to."

Staying on-label. "Prescribing information, prescribing information, prescribing information! You cannot talk off of prescribing information!" Janelle, a telephonic educator who provided education for patients with rare autoimmune and blood disorders, made this declaration to emphasize the requirement that clinical educators must always stay "on-label" when discussing a product. The prescribing information, which is also referred to as the package insert, PI, product label, or simply "label", is the FDA-mandated document that gives HCPs the information they need to properly prescribe

drugs and biologics (Kremzner & Osborne, 2007). It must accompany every prescription and is found on the product's website. Educators are well versed on the importance of not providing "off-label" information or personal opinions regarding their products. Examples of off-label topics would include an experienced side effect not listed in the PI, whether a medication can be taken with certain foods or other drugs not specifically noted in the label, or how the efficacy of the prescribed medication compares to another similar medication. As Yvonne, a diabetes educator, explained, "We are not supposed to give that product credit for anything that the FDA has not signed off on…It may do wonderful things…but if the FDA has not okayed it, doesn't matter. I cannot speak to it." Zara, another diabetes educator, explained how educators had to be particularly careful when talking about the efficacy of the drug to only make claims that are supported by the label. She stated, "Well, I guess you have to be careful what you say as far as what it will do. You have to be very careful about not making false claims."

Most educators found the inability to address off-label questions, especially those to which they knew the answer, to be demoralizing for themselves as well as the patients. Bonnie, a diabetes educator, bemoaned this fact as she reflected on the greater freedom she had working in the field. For example, as an office clinician, she could easily address a patient's request to compare the efficacy and side effects of two different brands of insulin. She would be limited or unable to do this as a pharmaceutical educator unless the drug she represented included that information in the label as part of a head-to-head comparison done during the clinical trials. She stated, "A person may have a question and we may be able to answer, but we may *not be allowed* to answer…I feel like I can't help the person as much as if I were working independent of a pharmaceutical company."

For others, the frustration was a result of the way compliance regulations would cast doubts in patients' minds towards the educator's skills or capabilities. Evelyn, an educator for multiple neurodegenerative conditions stated, **"**I perfectly know the answer and it's basic nursing knowledge or basic human knowledge, but you can't share it, so you sort of think, 'Oh God, I'm really sort of looking stupid,' but you just can't say it."

Lois, a telephonic educator who has multiple calls with her patients over the course of four to six months, described how repeated deferrals to the HCP caused frustration for her patients. She explained, "Sometimes they'll say, 'Well, why am I even talking to you? I should've just called the doctor's office.' That type of thing. 'You said, you can't give me your opinion. I want your opinion!' So that can be frustrating." Evelyn articulated a similar refrain, "You'd have to just review over and over that, 'I am permitted to talk about stuff on label and I can't go off.' You sound like a broken record, but I just was very careful about doing it."

Vivian, a diabetes educator, reflected on how patients would come to understand why she was not able to address some question, but would still leave the program discouraged. She explained, "They understood the necessity of why I was or wasn't allowed to answer questions, but they missed the learning, teaching moment, because they wanted to know now how things would work…I think it was kind of almost disheartening for them." Later in her interview, Evelyn recalled the experiences of patients for whom she provided multiple sclerosis (MS) drug education. In those instances, her deferral to a physician was problematic as patients would get caught in a cycle in which their concerns could not be addressed by either their clinical educator or their HCP. She shared, "It was like, 'Call your physician about it.' The really sad thing is

that most of the MS physicians didn't know anything about injections. The patients would call back and say, 'They don't know. They said to call you.'"

Adverse event reporting. The FDA requires that pharmaceutical companies document any reported adverse event (AE) or product complaint (PC) related to their medication (U.S. Food & Drug Administration, 2017a). In addition to product use errors, therapeutic failures, and the known side effects included in the product label, adverse events also include *any* untoward medical occurrence suspected to be related to the use of the medication (U.S. Food & Drug Administration, 2017c) As Antonia, an educator for neurology medications, simplified it, "And we report absolutely anything. If they tell us their nose itched on Tuesday, unfortunately we have to report it. I'm not exaggerating." As agents of the pharmaceutical company, clinical educators are required by law to document an AE whenever it is shared with them. Quinn, a diabetes educator, described the process by which she would document an AE, such as a patient presenting with headaches while taking a medication.

> Okay, well I'll sit down and ask them, "Tell me exactly how you're feeling. How long does this last? Is there anything that you do that decreases the feeling or this pain?" I'm writing everything down and then of course I'm going to call that in. And the more description, the more you can describe it, the better off it is to pinpoint what's going on, because that could be another drug, it could be a flu, it could be anything.

While educators are trained on the AE documentation process, and many of them admitted it was a common expectation of their role, it was not always an easy or straightforward process. The educators noted multiple challenges about AE reporting

that impacted their communication with patients. One difficulty as described by Antonia, an educator for patients with a terminal neurodegenerative disease, is that some companies encourage the patient to self-assess whether they believe the AE was related to the drug. She stated, "One of the questions you ask is 'Do you feel like this was caused by the drug?'…Sometimes they do, sometimes they don't…I get the information in their words, and we don't make a judgment…if they report it, I report it." A related problem, also described by Antonia, is that reporting AEs is a time-consuming process. She stated, "So, the reporting of adverse events I can tell you, takes about an hour. From the time you get the information to reporting it." She went on to explain how the process is especially problematic due to the progressive nature of the terminal disease her medication treats and that she engages her patients on a monthly basis. She stated, "If you have an in-depth discussion with a patient every month, I would say at least 70% of them have progressed…so if you were to be 100% compliant, seven out of ten calls would include a 15-minute adverse event report."

Another common concern articulated by some of the educators is the challenge of collecting the adverse event information without alarming the patient to the point they overreact. Janelle, an educator for multiple medications that treat autoimmune conditions, put it this way, "They also call in with adverse events. You know, 'This is happening, this is happening. Is this quote-unquote normal?' Patients always want to know if they're normal." Martin, a nurse practitioner and diabetes educator, elaborated more on this concept as he explained the challenge of collecting AE information from a patient in a face-to-face situation. He shared, "What do I tell the patient? You have to address the issue, but you have to think about their ability to understand this was

abnormal. It may not have been harmful, but it was not an expected outcome." Finally, Iris shared that a concern for her was that the requirement for clinical educators to collect AEs can create dilemmas even in the seemingly innocuous conversational pleasantry of asking a patient how they are feeling today. She described, "Even if the patient has a cold and they're taking your drug, that's a reportable AE. You can't say, 'How are you feeling?' And they're like, 'I didn't have a good night's sleep'…so everything is reportable according to the FDA."

The frustration with compliance regulations related to AEs, fair-balance presentation, and staying on-label sometimes boiled over to the point that educators pushed back against them, or simply ignored them. This typically was a result of educators' belief that the regulations' influence was having too great an impact on patient care. The next section examines these behaviors in detail.

Purposeful non-compliant communication. During interviews, some educators freely admitted to engaging in purposeful non-compliant communication behaviors, though not without deliberation. During a focus group, Tabitha lamented that the nature of the regulations presented educators with a "Sophie's choice"—a situation in which they must choose between two equally difficult alternatives. She said, "You walk away with one or two beliefs. Either 'I got it across to the patient, I succeeded in my mission'…or 'I didn't use any other words…and I was compliant. But I'm not sure the patient really got it.'" Vivian, a diabetes educator, reinforced this sentiment and noted that the goal of these education programs—promoting adherence behaviors that leads to treatment success—was at risk.

> You know you either fail your patient or you fail the compliance. With the regulations as strict as they are, often, when I knew I had to be careful, I left the session feeling like the patient really didn't get what they needed out of the class. But my [sales] rep was happy because I did everything by the book and dotted every 'I' and 'T' and didn't stray in any direction off script. But at the same time, I think that's the kind of patients that eventually fail treatment because they weren't going to be compliant because they didn't understand.

Vivian's qualifier of "when I knew I had to be careful" was reflective of her earlier one-on-one interview in which she felt that her need to completely uphold compliance regulation was often dictated by the presence of her pharmaceutical company's sales representative. She begrudgingly explained that, in those instances she felt inclined to follow compliance guardrails, even though doing so devalued her skills as an educator. She said, "Some classes, I was on my own. I never saw a rep. I would answer stuff that I was probably not supposed to." Iris was much more forceful in her criticism. She believed that the expectation to use a program script not only devalued and disrespected her and her ability as a nurse, it disrespected the patient as well. She stated, "You could just have an answering machine to do that…Tell me what it is that you need, what information you need. Give me the respect that I know how to get proper information, an answer you want from your patient."

Later in her focus group, Deandra shared that a decision whether to go off script would sometimes be dictated by the type of program she was presenting. She explained that she felt more comfortable deviating from the approved materials of her pharmaceutical-sponsored disease-state programs—those in which the topics were

disease pathology and lifestyle management—as opposed to product programs in which she was instructing on the safe usage of a company's medication. She explained, "[The pharmaceutical company] is not going to jump down my throat if I present it as, 'This is like an army and this a sergeant' or whatever…But when it comes to product discussion, way more watching out what I'm doing."

During the focus groups, educators were asked directly if they felt the educational scripts and materials provided to them were written beyond the comprehension level of a patient, whether it was acceptable to "go off script" and bring it down to a level the patient would understand. Educators who supported going off script provided rationalizations related to the necessity of trying to provide education at the learner's level. Sophie, a diabetes educator, was supportive of going off-script if the situation merited it, "If the whole purpose is to educate the person, then you may need to bring it down to their level…Again whether that's through a drawing or rewording something to help them understand that. I do think that's appropriate."

As a follow-up to that question, educators were asked whether they thought pharmaceuticals company give tacit approval to go off-script in situations in which an educator deemed it necessary. Sophie believed that the companies would give that tacit support if their goal is to have their patients be compliant with their medication. She noted, "I would say if they as a pharmaceutical company would like the patient to successfully continue to use their medication, I do think that they would give a nod to that." Others, however, were not as optimistic and noted the discord between the companies' public promotions of patient-centricity and the private legal ramifications that drove much of their decision making. Iris stated, "I don't think the company gives

approval because they constantly say we couldn't…Their top concern is the legal ramifications of everything we do… though they say that they are interested in the patient and it's patient directed…it's to sell drugs." Tabitha sympathized with a belief that while the companies would ultimately like to give educators discretion to adapt programs to patient needs, ultimately their liability concerns would always take precedent. She reasoned, "I don't think they can give tacit approval for something like that. They probably would want to. But I don't think they really can. Their job is to tell us what our role is and what being compliant is."

While multiple educators admitted to a history of breaching compliant communication guardrails, or a willingness to do so in the future, three of them—Antonia, Iris, and Tabitha—provided passion-driven rationales that extended beyond mere frustration or annoyance with the regulations. Their justifications for non-compliance were driven by personal philosophies that put unfettered patient care as the primacy of their role. These educators fully understood the logic of compliance regulations and the liability implications for violating them. However, they struggled when those regulations hampered patient care. Additionally, while all three admitted to violations, they did not blithely disregard all compliance regulations. In fact, as was evident in their interviews, they had a profound and deep respect for them. Their decision to be non-compliant was not a reaction based on disrespect for the institutions they served, rather it appeared to come from what drives rebellions—a passion for change.

The remainder of this theme explores the non-compliant communication behaviors as illustrated through the experiences of Antonia, Iris, and Tabitha. These

stories exemplify how factors within the political/legal context (i.e. compliance regulations) can influence communication behaviors that are opposite of their intent. The goals of compliance policies and regulations are to provide structure and guidance for the educators while also promoting clarity and preventing errors during their interpersonal engagements with patients. However, these three educators felt they provoked confusion and eroded trust. As such, the resultant frustration and confusion compelled the educators to respond with actions that were counter to the regulations' goals. Additionally, as will be explored in the next theme, as well as in the Chapter 6 Discussion, the ability of these ecological factors to simultaneously promote and impede compliant communication behaviors forced many of the educators to experience ethical dilemmas regarding their role. Antonia's, Iris', and Tabitha's stories help provide a foundation for understanding why those ethical dilemmas were pervasive and troublesome.

Antonia was one of the four participating educators who provides full-time coaching and education services on behalf of a single client, a pharmaceutical company that manufactures one of the few drugs that treats a rare and terminal neurodegenerative condition. The drug, which is administered in the physician's office or at an infusion center, is not curative, it only slows the progression of the disease. The condition is not easily diagnosed and tends to progress quickly once identified; most patients die within two years of starting the medication. Antonia's role is educating patients on the medication as well as serving an on-going navigator who provides support in the form of infusion coordination, side-effect management, payor services connections, and disease

management strategies. Antonia engages with her patients either in-person or over the phone approximately once a month.

Antonia started her healthcare career as an RN in neurology before spending many years as a pharmaceutical sales representative. During her interview, Antonia shared two catalysts that spurred her change from pharmaceutical sales to clinical education. The first catalyst was the personal experience of caring for a relative's child with a terminal disease. The second facilitator of her role change was the uneasiness she felt while watching healthcare professionals, whom she sold medications to as part of her sales role, send patients home improperly trained on those medications. She explained, "I was uncomfortable if healthcare professionals were basically going to send the patient home even though I knew they weren't qualified. I didn't feel like they were safe, or they could do it in a sterile environment."

For Antonia, "time" was the enemy of her patients for reasons beyond the mortal nature of their disease. She believed that it was often something many patients were denied in their educational interventions. She stated, "…the biggest obstacle always in education is time, because some patients, you could teach them how to give themselves an IV medication in a half an hour and other patients take three hours. But you don't really have three hours." She felt that before even broaching the technical components of training patients, "you need to get a baseline relationship with them, and they need to develop trust in you and that takes time." She went on to explain why establishing a baseline relationship is important. She noted, "You really have to say, 'Tell me about your journey. What are your struggles?' So, if you have a half an hour, you still need to spend ten minutes on that or they're not going to hear the final twenty." Antonia

confessed that she allots time for patients beyond her company's expectations because she values its importance to the relationship. She shared, "I tell my patients, 'I'm here until we both are comfortable that you understand.' So, having that kind of trust. 'I'm not leaving. I'm not in a hurry. I'm here until we're both comfortable with what you need.'"

Antonia explained that there is an emotional element to her role that is not typical of clinical educators who work with chronic disease patients. She clarified, "So in this job, first of all, I'm working with people who have or have recently been diagnosed with a terminal disease. So that adds a whole emotional element throughout the theme of every visit." In fact, during another point in her interview, she estimated the amount of time she spends dealing with the emotional components of her role. She stated, "So, it's frustrating because I believe 80% of what we do in terminal diseases is emotional support." She went on to suggest that the trust that she builds with patients throughout the tenure of her support service is what ultimately cements an emotional relationship with them. She explained, "They invite their family, they invite their church people over, so I'm a part of their lives. I really feel that keeping the trust... Because I need to keep—this is a long-term relationship—I need to earn their trust, long-term."

Interestingly, it was only after the interview had ended, and without prodding, that Antonia felt compelled to fully reflect on her experiences of working with dying patients and how that impacted her emotional health. She mused,

> One piece of this which I didn't really talk about is that there's a lot of loss. We're trying to help our patients and they die. And when you have a relationship with someone—sometimes I'll lose two patients a week—dealing with the grief is hard. We're advised not to go to funerals. We're advised not to send cards. But

> that's a big portion for us…And I have to tell you, people ask me, I would say out of a five-day work week I cry three days…I mean you get choked up. You don't start balling. But you hang up the phone and you think "Shit. Shit."

Like Antonia, Iris felt there was an emotional element to her role, though in her case, it was passion. In fact, during her one-on-one interview, Iris jokingly responded to a comment regarding the passionate way she spoke of her work and her role by saying, "Oh, that has gotten me in so much trouble. I'm Italian, that's my background. It's gotten me in a lot of trouble many times. But I'm so glad that you say that it's passion and not anything other than that." Iris is a clinical educator who has spent more than ten years training patients on medications in many different therapeutic areas including neurology, rheumatology, gastroenterology, and geriatrics. She was an introspective individual who lives her professional life centered around a core belief that, like Antonia, was grounded in trust. As she explained it, "You learn something that becomes the center core of how you go, you always come back to that one thing… 'be in the place where your patient is'. You're not going to reach a patient if you can't do [that]." Later in her interview, Iris elaborated on this core belief and how it was refined by a simple Buddhist principle. She stated,

> [Trust] is a lacking thing in our society and more and more, it becomes so important…Do you know the Buddhist concept of loving kindness? ...It is being able to recognize and consider, to look at that person and truly in your heart consider what their need is. That's that nonjudgmental thing. It's that going in where the patient is and being able to truly have their interest at heart.

Iris was similar to Antonia in other ways. She was also in her sixties and had a long career that included hospice care and working with patients who were dying. Her experiences in treating patients nearing the end of their lives influenced how she approached her clinical educator role, particularly regarding the older patients with whom she frequently worked. She described how older patients, especially those who recently lost a loved one, were at increased risk for health issues such as hypertension and the onset of other diseases. Therefore, she believed part of her role was to broaden her educational engagements beyond the approved management strategies of her company's medication to include a broader scale of coaching and lifestyle-management tactics. She described it this way. "Working with them, encouraging them. 'Make sure you make this doctors' appointment.' Then working with them with their side effects, telling them who to report to and that's important, or 'Let's think a more about this. What can we do?'"

Like her two peers, Tabitha has a long and diverse career that included time serving patients at the end of their lives. After working as a nurse overseas, she settled back in the U.S. as a diabetes educator. Tabitha was never employed full-time on behalf of a pharmaceutical company. Instead, she served as a contracted educator who was paid on a per-program basis. Tabitha had beliefs similar to Iris and Antonia about the nature of trust in her clinical educator role. When asked what she had learned throughout her career about the way to communicate with patients, Tabitha reflected on her time as a hospice nurse. She had learned that trust was at the foundation of her relationship with all types of patients, and that keeping that trust was contingent on open and honest communication—even when patients were nearing the end of their lives. She explained it this way, "Those patients need to trust you. Even as a hospice nurse, the level of intensity

and emotion between the patients and you instantly is established…You have to be able to tap into that very early on in the relationship."

Tabitha worked primarily with patients who had diabetes and osteoporosis during the latter part of her career. However, it was evident that her earlier experiences in hospice and nursing abroad influenced her views about how to engage patients with common chronic conditions. She explained how she took advantage of working in multi-practice offices with shared waiting rooms. She would often address her chronic patients' "fatalistic" views about their disease by reminding them that, unlike patients with a terminal disease, there were options. She stated, "For chronic disease…people get fatalistic. Often, I'd say, 'There's more things life can hand you than diabetes…Did you sit in that waiting room next to anybody with a bandana on because they're going for chemo? …We've got options for you.'" Tabitha concluded her thoughts by expressing a sentiment that seemed to be at the core of her personal belief system regarding patient education. Her notion of "you still have control" not only served as a message of empowerment to her patients, it mimicked the medical ethics' principle of autonomy and spoke to the role such ethics played in how she communicated. She reflected, "You have to let people know they have control over what's happening to them. That dying patient may die in 72 hours, but in those 72 hours they have control…You have diabetes, it's not curable, but you still have control."

For these three educators, the need to build and maintain trust, as well as the need to respect patients, their time, mortality, and autonomy, served as primary rationales for purposeful non-compliant communication. The high value Antonia placed on both time and a trust-based relationship with patients were reasons why she chose to occasionally

defy the rules. For example, Antonia rationalized her and her colleagues' willingness to keep hand-written notes about patients and their families, a compliance violation, was necessary to avoid breaching trust with individuals she viewed as already emotionally fragile from the desperateness of their situation.

> Patients that are terminal are desperate and they're desperate for someone to understand them…Nowhere are we allowed to write down the fact that John and Lisa have two children and their daughter got breast cancer and the wife was diagnosed with Parkinson's the week she was diagnosed with [neurodegenerative disease] and all those facts. We have to just remember that…[But], this is the part that no one talks about…I personally have a hundred patients approximately. There's no way I can remember all these things. And they're important to the patient…So most of us, myself included, keep notes…Otherwise I look like an idiot every time I call them…I literally have a patient that was diagnosed with breast cancer the week she was diagnosed with this terminal disease. If I forgot that when she called me, how dumb would that be?

Antonia used the justification that she was preventing a trust breach when admitting to actions she took in another situation that bordered on being non-compliant. Antonia explained that she often struggles when her patients asked her questions about the availability of an oral version of the medication she supports that currently can only be administered as an intravenous (IV) infusion. She grumbled,

> Everything I do I think about compliance. For example, there's stuff online about my drug that I can't say. And patients ask us questions all the time. My drug is IV. It's common knowledge that they're researching an oral version. When the

> patients ask me about that I have to say, "I'm not allowed to respond to that." I feel like it damages their trust in me. Because I know full well that they're researching oral, that my drug is being researched. It goes out in the newspaper; anybody can Google it. So why do I have to pretend like I don't know about it?

She went on to describe how she responds to patients when faced with this inquiry. She explained, "I don't know if this is compliant, I tell them every IV drug launched is studied as an oral, because it's the easiest and safest. So, it's a matter of time. That's as much as I say because I'm restricted." Antonia defended her actions by describing a strategy she uses that she felt was a reasonable workaround and one that avoided further non-compliant behaviors. She explained what she says when she does a periodic follow-up call with her patients' physicians. She said, "I'll say, '[Patient] is really excited about the concept of oral medication. If you have the ability to look that up, I'm not allowed to address that.' The clinics like when I tell them that because they trust me more." While Antonia did feel hamstrung by these compliance limitations, she also made sure that her patients understand their rationale, so as to not cast a negative light on her company. She shared, "I tell them, 'The reason that I'm limited to what I can say is patients diagnosed with this disease are vulnerable. And companies can't walk around saying what they want. They can only say what the FDA approves.'"

Like Antonia, Tabitha knowingly violated compliance rules because she was able to justify doing so. As an example, she rationalized that providing her personal phone number to patients was a reasonable, albeit non-compliant action, because doing so promoted patient autonomy. She felt that her medication's self-injection process was not always something that patients could master during a single training intervention and

therefore, wanted to provide an additional means of support. She explained, "I would do something that was totally against the rules. I would give patients my home number and they would call me. [Pharmaceutical company] would have went crazy, but I did do that… Because I knew how lonely you feel."

Even though Tabitha initially stated that giving out her phone number was her only violation, she would admit later in the interview and in her focus group to more non-compliant actions. Each time she was able to defend her behavior. For instance, she described how physicians would occasionally send patients that were not prescribed the insulin she represented to one of her insulin group education classes. She was expected to turn those patients away. However, she rationalized that allowing them to attend was in their best interest. She stated, "Sometimes there were ten patients on [company] insulin and two on [different company] insulin. I was to turn [the two] away but couldn't do it. I'd let them sit in. That's another non-compliance thing, but they were always so happy."

Iris' primary justification for her non-compliant actions were centered on her respect for patients. This meant providing them with the information they needed in ways they could understand it. She stated, "The best teachers give you what you need, respect you and your opinion and decision, be non-judgmental…That's part of loving kindness, you're going in to offer them information you have. That doesn't make them less than you in any way." However, just as important as her respect for her patients was her respect for herself. For Iris, the question of whether to be compliant would always come down to a sense of personal integrity. That integrity would not allow her to bend to

what she felt were indefensible compliance regulations out of blind allegiance to a pharmaceutical company. She shared that belief in the following way,

> I don't believe I can change a whole lot. I can only change one thing, and that's…that patient and the job that I have with that patient. I can't change the world, but maybe I can do one little thing one day at a time. That's all I can do because I don't have the power to do anything else. But it's my integrity. You see what I'm saying? I can't walk away from a patient's house and say, "Oh, that damn drug company made me teach her that way," because that's my integrity.

Iris and Tabitha both expressed their greatest compliance grievances toward the expectation that educators were not to deviate from, or adjust, approved language and materials, even if they felt doing so was necessary to meet patients' perceived comprehension level. In fact, Tabitha believed that if she delivered the program using the language and materials exactly as they were to be presented, she would never be successful. She explained that once she was alone with the patient, her primary goal was to get the patient to understand the information and be comfortable in administering their medication—by any means necessary. She stated, "If we held to the letter of the compliance law, we'd never be able to do what we did…But once the door closed, I had one goal—to get you to understand…Any way I could do that, I would."

Tabitha criticized regulations that prevented her from adapting program materials because she felt they failed to account for patients with limited health literacy or poor language skills. Thus, she believed being compliant put a patient's safety at risk. She explained it this way, "Frequently, [material] was written to high school levels. I have somebody that barely speaks English and they have to know how to titrate insulin. What

am I to do? I'm going to read this to them!? Are you kidding me!" Iris shared a similar experience of patient safety needing to come before compliance. In her case, she believed that the instructional materials provided by her client were poorly written and unsafe. Therefore, patients were at risk for giving themselves an unsterile injection. She explained,

> I'm working in a program now where they always tell you, "You can't cross anything off, you can't change any of the material, blah, blah, blah. Don't write on the material." Well, the way that they outline for the patients who take an injection, if the patient washes their hands and then goes through 15 steps before and they now have a needle and a syringe up in the air that's open, and now they have to take down their clothes and prepare their belly. That's nuts! You know what? Fine me! Do whatever, fire me. I'm not going to have an 80-year-old lady lay down the open needle she was holding in order to pull down her panties. I'm trying to teach her how to give a sterile injection. Come on, she's got to pull down her panties in the beginning. Everything's got to be ready!

At the heart of Iris' frustration was that she perceived the programs to have been designed by individuals without expertise in adult learning, health literacy, or behavior change principles. For her, pharmacologists and marketers were not education experts. Or, as she stated, "'Hey, listen to me, do you want an architect or a chef to design your kitchen?' That's what these companies have to realize…engage nurses in the way you're addressing patients because we're the ones who are delivering it."

While Iris' frustration left little sympathy toward her employers, Tabitha was more supportive. In fact, among all twenty-six educators, she was the most vocal in a

defense of the pharmaceutical industry. Tabitha would use phrases like "skirted the compliance thing" or "almost compliant" to downplay the severity of her non-compliant behavior and even imply that, though her companies' sales representatives would never publicly acknowledge such, they understood and supported her actions. The following statement highlights this belief, "They understood, but did their due diligence as we took classes ad nauseam about compliance…The reps understood these regulations were hard to follow and didn't benefit the patient…So we were close to compliant. Kind of like almost pregnant, almost compliant." In fact, Tabitha believed that while she did choose to engage in non-compliant communication behaviors, her actions were not egregious enough that they would warrant severe discipline. She explained, "I had a loyalty to [pharmaceutical company]. They were very good to me for many years. Anytime I kind of skirted the compliance thing, it was never something that a thinking person would really want to totally crucify me for."

Tabitha, like Antonia and Iris, often assessed her compliance dilemmas within the medical ethic of autonomy and her responsibility to provide information that allows patients to take control of their condition. She had brought this notion with her from her prior experiences working in hospice. She would often remind those patients that, even in the final stages of life, she was there to support their wishes. As she stated, "You're dying, but you still have control." Antonia, whose network served patients with a terminal condition, similarly spoke of the importance of maintaining trust and autonomy over all other things when she said, "I'm a part of their lives now…this is a long-term relationship, I need to earn their trust, long-term." Iris reflected on an ethical situation in which she was needing to provide product training for a patient who had previously

received a radiation treatment that was contraindicated to the use of the drug she represented. Though Iris expressed discomfort with the patient's decision to proceed, she explained that she ultimately needed to respect the patient's autonomy given the patient's awareness of the potential risks. She described the experience this way, "It made me feel really uncomfortable, but I had to respect her decision…I wasn't going to say, 'I'm not going to train you,' because she made a conscious decision knowing…She understood it and she wanted to take that risk."

Tabitha's, Iris', and Antonia's actions demonstrated how the influential nature of political/legal context factors can sometimes result in outcomes that are opposite of their intent. The rigidity and complexity of government and industry regulations generated backlash when held up against these educators' deep-seated beliefs about the nature of their role. In fact, throughout her interview, Iris did not hold back from admitting that she would freely deviate from compliance regulations when they conflicted with her professional ethics. She shared an example of a catalyzing situation she faced when she perceived the risks of the multiple sclerosis medication she represented began to outweigh its benefits for some of her patients. She confessed,

> I worked with MS patients on lifetime long-term injections. These patients are diagnosed in their 20s and they may take [these] drugs. They're now in their 70s and they might have been taking them all that time…I would go out and see these patients that had huge necrotic wounds, wheelchair bound from no muscle, no fat left. Areas of big wounds from this drug. At what point when you're 70 years old or 80 years old should you still be continuing this drug? So, risk versus benefit has changed and here I am representing and trying to tell them how to manage

> taking this drug when I believe that they shouldn't be taking it. So that raises a real question because I want the patient to trust me and I want that patient to know that I care about them because what I do is not worth anything if I don't care about the person that I'm serving.

Tabitha's described a similar tension that existed as she felt equally duty-bound to protect her patients and the pharmaceutical companies. She was able to reconcile this dissonance by rationalizing her non-compliant actions; she thought that she was never endangering the safety of her patients. She stated, "I think the pendulum has swung so far that, I never believed I endangered really, giving my home phone number was the most radical thing. Many patients utilized that, and I felt so good and they were so grateful." The loyalty these three educators felt to both their patients and their employer was a common ethical dilemma experienced by many educators. In fact, this sense of "dual loyalty" was pervasive enough throughout the interviews that it rose to be one of the primary topics of the next theme in this chapter. That theme examines how the influence of political/legal context factors forced educators to deliberate the ethics of their role.

Ecological Factors and Ethical Dilemmas

Theme 2: The influence of ecological factors, particularly within the political/legal context, would frequently force educators to experience ethical dilemmas.

For the most part, influential factors within the political/legal contexts provoked challenges and barriers that, though frustrating, were frequently resolved by the educators with little ethical deliberation. However, that was not always the case as evident from the insights and experiences of Iris, Tabitha, and Antonia, who often struggled with moral predicaments. The rationales they used to resolve those conflicts were rooted in

constructs such as professional integrity, respect for autonomy, and trust maintenance. This theme explores other examples of the relationship between ecological factors and ethical dilemmas and how similar logical and moral constructs were used in many clinical educators' deliberations. The ethical dilemmas presented here are organized within the framework of three dual loyalty contexts—situations in which educators needed to choose between two equally deserving alternatives. Those dual loyalty dyads include patient versus the pharmaceutical company, patient versus their HCP, and patient versus their family.

Dual loyalties: patients versus pharmaceutical companies. Deandra, an educator for autoimmune disease products, used an analogy to emphasis a common tension of her role. She stated that she felt like a puppet of the pharmaceutical company when she was expected to parrot their approved message at the expense of patient comprehension of the materials. She asked rhetorically, "…do I step outside the regulations and get my job done and make sure my audience understands it or do I just stand there like a puppet and recite what the regulations tell me to say and walk away?" Her concern exemplified a dual loyalty deliberation described by many of the educators—a competing sense of loyalty and duty between the interests of the pharmaceutical companies that employed them and the patients for whom they served.

Educators were disheartened by what they believed were misplaced priorities by the pharmaceutical companies regarding the educational programs and their intent. Multiple educators decried the companies' focus on the quantity of delivered programs over their quality. Bonnie, a telephonic educator for many different products, expressed a frustration in that regard. She lamented, "It's more about numbers, it's more about,

unfortunately, quantity than quality and a lot of cases…At the end of the day, the email I get is, 'This is how many calls you need per hour.'" A similar criticism was voiced by Cora, another telephonic educator for many different products, who believed that her companies' emphasis on volume was shortsighted and counterproductive. She felt that the amount of time necessary to accurately assess a patient's barriers was at odds with the companies' numbers-based focus. Hence, long-term adherence to the medication was at risk. She explained it this way, "We're moving into a whole different spectrum of just looking at how many calls per hour…it's getting away from the holistic style where we're spending time with the patient and assessing their strengths and barriers, what they need to learn."

Adherence to compliance regulations was often implicated as one of the most common causes of moral distress. In Iris' view, the companies' expectations for strict adherence to those regulations was an outcome of their fears of legal culpability. She stated, "…pharmaceutical companies try to prevent, their first view, their absolute top concern is the legal ramifications of everything we do. And that's the way I feel." Antonia described how those regulations eclipsed her duty to a patient who she felt was at risk for harm because of unsafe HCP practices. As she explained it, "I feel like there's some disparity in our roles because I'm so limited to talking about…I had someone talk about some very unsafe port practices from their infusion clinic and I'm really not allowed to do anything about that." Iris shared a series of rhetorical questions to emphasize the internal struggle she faced with her patients who were prescribed the MS medication to which she believed the risk/benefit balance had changed "There is no little pharma bird on the wall listening to everything we say. So, it becomes an ethical

question. What do I do ethically? Where is my first responsibility? Is it to this patient or to this drug company?"

Dual loyalties: patients versus healthcare providers. While educators frequently struggled with competing loyalties between their patients and their pharmaceutical companies, it was not the only dual loyalty dilemma they faced. At times, educators found themselves at crossroads that put patients against the providers who treat them. In some cases, educators felt obligated to support the HCP even if they believed the HCP was providing inappropriate care or not acting completely in the patients' best interests. Martin, a diabetes educator, stated it succinctly, "…even if we recognize that a healthcare provider was not treating the patient correctly, we could not relay that to the patient." Antonia articulated a similar refrain. She stated, "I have to be very careful. I never ever talk negatively about a doctor, never. A patient needs to have trust in their doctor. It would have to be pretty dang bad for me to." Olivia, an educator for terminal neurodegenerative disease patients, explained that she frequently felt obliged "to make nice" to patients on behalf of their doctors even when she believed the physicians were not providing the best care. She lamented, "[Patients] will cuss out their doctor to you…and you're thinking all the same things that [patients are] saying but you're just telling them 'It's us. We're asking so much of [physicians].' We're always making nice on behalf of their offices."

While educators often found themselves in a position of defending the physician to a patient, the reverse was also true. Cora, a telephonic educator for numerous conditions, discussed having to advocate to physicians that providing educational services and materials to patients was not a futile endeavor. She had encountered HCPs

who felt some patients were unreachable. She stated, “You have some [physicians] that champion what you do and are very thankful…then you have some that are not, that just see it as…some people are just unreachable…that's sad because I think everyone is reachable. It's just figuring out how.”

Zara, a diabetes educator, shared a similar frustration when encountering patients whose physicians had not informed them of their diagnosis or provided any preliminary disease education. Unfortunately, as she was unable to offer medical advice, she was limited in the response she could provide. She believed those patients were frequently the ones whose diabetes would get out of control. She shared, “I get patients whose doctors don't even tell them they're diabetic…just given the insulin and don't give any education…then you wonder why people are out of control because they're not taking their insulin because they're afraid of it.” She continued by voicing additional annoyance with what she believed was physician laziness. She felt that some HCPs resorted too quickly to prescribing medication instead of allowing time for patients to try lifestyle changes for diabetes control. She also felt some of her physicians were lax in their responsibilities by not referring their diabetes patients to endocrinologists, opting instead to treat them themselves. She begrudgingly noted, “[Physicians] may push, let's start medication without really encouraging the patients to try lifestyle change. They don't even refer patients because they don't want to take the time to do it, and that's really sickening…They're lazy.”

Dual loyalties: patients versus families. Clinical educators often trained patients in the presence of family members who served a range of supportive roles—from a simple emotional advocate to full-time assistive caregiver. Not surprisingly, disease

and therapy related stress would sometimes give rise to situations that pitted educators' loyalty to their patients against the family members who were supporting and caring for them long-term.

Olivia explained how her role as an educator who met over the course of a year with patients with a terminal neurodegenerative condition sometimes included serving as a mediator between the patient and family members. She shared an example that illustrated how her intervention served a larger purpose beyond helping families make a healthcare decision. She believed her mediation was actually part of her larger responsibility to provide the requisite empathetic and emotional support necessary for families facing the impending death of a loved one. She explained it this way,

> I've gone into homes where there'll be a patient and her sister. You're trying to go through the welcome kit with them, and all of a sudden the sister will be like "And she doesn't want a feeding tube". The patient's looking at you, and she's like, "I don't HAVE to have a feeding tube." You're like, "They want me to mediate this discussion for them." You're thinking, "And this feeding tube has not a darn thing with what I'm here for." But you're in that position, and they're both looking at you, and they're expecting you to be on their side, right?…That is the kind of stuff that this is about. It's not always just about [drug name] …They don't care about that. They want you there for other emotional things, so it's very interesting dynamics.

Other educators found themselves in even more tenuous family situations that forced ethical deliberations. Quinn, a diabetes educator, described an experience she had of training a young girl who she suspected was being abused by her father. She

explained how she felt mandated by her role as a healthcare professional to report her suspicions and therefore actively engaged her sponsoring company's assistance in doing so. She stated, "One girl had ligature marks around her wrist...When I walked out of there, I called the [pharmaceutical] company…And they said 'You're a nurse, you have to do what you have to do.' So, I did it. I called and reported it." Antonia was similarly faced with an ethical situation. A patient's family member disclosed to Antonia that she was thinking about committing suicide. Antonia felt morally and professionally obligated to intervene in such a situation, even though the family member was not her actual patient. She believed part of her role as a health service provider for patients included taking care of their family. She shared, "When you take care of a patient, their family is really your patient too…So that was a real difficult one for me because she wasn't my patient. But some things we are, as healthcare professionals, required to divulge."

Iris reflected on a similar moral dilemma related to patients' mental health. She explained that when suicidal ideation was disclosed to her by a patient, it was an easy ethical situation to resolve. She was legally and professionally obligated to report such an event, even when serving in the capacity of a pharmaceutical-sponsored clinical educator. However, she felt there was less clarity regarding her responsibility to a patient's family if a patient exhibited mental instability that was less imminent or clearly life-threatening. She struggled with the limitations of her role as a pharmaceutical educator that stymied her, both legally and ethically, from intervening, regardless if she believed it was in the best interest of the patient. She explained, "Here's the ethical question. If I have an older patient and I question their judgment and their mental status,

do I have a right to call their child and say, 'Something's going on here.' No, I don't. That is difficult."

Educators believed the political/legal context was one of the most influential, if not *the* most influential, factor for determining how they communicated with patients. Those factors were integrally related to the ethical dilemmas educators would sometimes face as part of their role. However, transcript data revealed another set of factors that had a compelling impact on patient engagements that did not fit within any of the other contexts noted in the literature. The next theme examines a proposed context called "disease and treatment" that seeks to account for those factors.

The Disease and Treatment Context and the Clinical Educator

Theme 3: A sixth context, the disease and treatment context, not previously identified in the ecological model literature, emerged from the interviews as having significant influence in the conversation dynamics between the educator and patient.

Throughout their interviews, the clinical educators frequently reflected on how the nature of the disease itself, as well as its treatments, were influential in the way they would communicate with patients. Educators used an analogy of the disease journey to illustrate how they and their patients viewed disease in the context of an ongoing series of experiences that were traversed. Some disease journeys had clearly demarcated progression benchmarks while other were less well defined. As most of the educators worked with patients afflicted with treatable and manageable chronic conditions, those journeys tended to not have a clear end-point destination such as "cured." Rather the goal of the journey was to reach confidence and comfort in the self-management of the disease. The disease journey was characterized with factors that influenced the way

patients would communicate with educators. However, some of these factors did not fit within any of the parameters of the five existing contexts noted by Street (2003) and Head and Bute (2017). Therefore, a sixth context, the disease and treatment context, is proposed for this study. The remainder of this section examines five factors identified in the data that comprise this context and how they impacted patient-educator communication. They include disease type, disease-related side effects, treatment-related side effects, prevalence of comorbidities or disabilities, and drug administration modalities.

Disease type. Most of the participants had experience working across multiple therapeutic areas both as a field educator and a pharmaceutical-sponsored clinical educator. All the educators, at one point in time, provided pharmaceutical education for products indicated for common chronic conditions including the four educators who were employed full-time to provide services for a medication that treated a rare terminal neurodegenerative disease. Additionally, most of the educators had prior field experiences working in areas beyond chronic disease management such as in acute or trauma-related conditions, surgery, oncology, rare diseases, and palliative/hospice care. Throughout their interviews, these educators would frame their beliefs and experiences about interpersonal communication with patients within a comparative context of common chronic versus non-common or non-chronic disease.

Janelle was an educator for both in-market and clinical trial medications that treated a range of ailments, from common chronic conditions to rare and potentially terminal diseases such as primary immunodeficiency (PI), hemophilia, and phenylketonuria (PKU). She explained how educating a patient with a rare disease

required a "higher touch" type of engagement than for those who were a common chronic disease patient. She noted, "[Rare disease] patient populations need much more high-touch…because it's so rare, it seems like you're the only person on the planet that has it…there's a lot of hand-holding and a lot of therapeutic listening that goes in with those patients." Janelle continued by explaining that one of the differences of helping patients with rare diseases is that they tend to feel more secluded. In fact, she described how some of her patients would share with her their belief that their physicians did not even understand the disease. She said patients would make statements to her such as "Well, I don't think the doctor understands this because it's so rare, and I'm their only patient that's even on this medication, and I don't think they understand it!" Adding to those patients' struggles was that the medication administration process for some rare diseases involved complex and invasive procedures like self-infusion. She described it this way, "You were educating patients constantly and their families on these really rare disease states; hematologic disease states that they didn't understand…And the infusion process to teach patients or caregivers how to give these infusions was quite the uphill battle."

Similarly, educators would engage with patients who had a terminal prognosis differently than their patients with treatable chronic conditions. Iris, an educator who trained patients on a medication for autoimmune conditions but had prior experience working in hospice and palliative care, acknowledged as much when she asked the rhetorical question, "So am I going to talk to…someone who's just been given a horrible terminal diagnosis compared to someone who is really engaged and says, 'Okay, I'm ready. This is an issue…I know I can fight this.'" Penny considered the depth of conversations she had with terminal disease patients to be much greater because they

tended to focus more on the value of life. She explained, "So, education…you still tailor it based on their needs…But if there's a terminal thing involved, you tend to focus on what matters and really question life. And then the conversation becomes deeper."

Evelyn lamented that the rare terminal neurodegenerative disease for which she provides medication education had unique challenges that changed her instructional approach. One issue was that, because of the rareness of her patients' disease, it often took a long time to diagnose or was frequently misdiagnosed. She remarked, "It's a diagnosis of exclusion. Frequently patients have gone months or years getting misdiagnosed…It's not like when you have a strep throat… you get a test, you get the medicine, you're done, your test is fine, you're feeling better." Adding to the frustration was that, unlike other neurological conditions such as multiple sclerosis, there was no way to verify that the medication she represented was working. She stated, "You can't test how the medication is working…With MS, you can follow the imaging and you can see changes in the imaging or no changes. With [neurodegenerative disease], you're following the progression of the disease. It's a little bit different." Evelyn admitted that these issues provided a greater conversational challenge for the neurodegenerative disease medication than the hypercholesterolemia (high cholesterol) drugs on which she once trained. She described it this way, "It's a little bit different than the hypercholesterolemia medicines. They take the medicine, then they look at their LDL level. That kind of reinforcement…It's easier, and that's something very specific. When you're teaching them, it's a much easier situation."

Olivia, one of Evelyn's teammates for the medication that treated the neurodegenerative condition, came to her role having previously working in palliative

care. She shared how she learned through her hospice role of the value of engaging the family in the emotional experiences of terminal diseases. She carried that belief with her to her pharmaceutical role. She shared, "With hospice you're incorporating the entire family because you have this extended group around folks because they're dying…It's always very, very emotional and volatile, so you're always trying to center things about a lot of emotional support with the education." Interestingly, unlike any of her peers who worked with dying patients, Olivia was the only educator who shared an introspection of the way she believed patients sometimes adapted *their* communication to fit *her* emotional needs. She described how this behavior was unique to her patients with the terminal neurodegenerative condition as she had not experienced it from other patients with whom she had previously worked. She mused,

> For whatever reason, with [terminal neurodegenerative disease] these people now have this life sentence, and they know what the outcome is, and they're all like happy and grateful. I have never in my life worked with a population of people that are so kind and so gracious and so lovely. Like they come to this acceptance, and they have this joy and this peace and this sense of wonder, and it is unbelievable to me…So, in some ways you almost would want to be like kinder and gentler…they don't require any extra handling because they're handling you like that…They're like, "Thank you so much, and you're such a joy and such a gift, and God bless you." And you're like, "Are you even kidding me!?" They are so good to me. They fill my bucket.

Disease side effects. The way a disease progressed would sometimes result in side effects that educators would need to account for when interacting with patients. For

example, in some instances, a side effect was simply the silent nature of a disease that would present issues. A silent disease means the condition progresses asymptomatically until the later, more damaging stages. The educators noted that even after a diagnosis, if a patient did not experience some direct or physical manifestations of their disease, they could be lax about taking self-care actions. Felicia, an educator for a self-injectable medication for osteoporosis, noted that this was often the case with her patients. She stated, "I think the main thing is that, with osteoporosis it's a silent disease. They don't even know that they have it, they don't believe that they've had it." Adding to Felicia's challenge was that the daily self-injectable biologic on which she trained, though efficacious, would not produce outcomes that were physically perceivable by the patient or easily measurable by the HCP. She reflected on her prior role as a wound care nurse to highlight this difference. She stated, "A wound was so simple, you measure it once a week…With a lot of these [osteoporosis] women, you don't even know you have the disease, but now you've got to commit to two years of treating something…it's a hard commitment."

Quinn, a diabetes educator who also had experience delivering education for a multiple sclerosis medication, noticed that a lack of perceivable progression of a disease would often encourage patients to take a gamble by delaying treatment. Unfortunately, in the case of MS, once it progressed, the damage was irreversible. She would tell her patients, "You can let it go and take the risk of your MS not progressing, but once it does, you're going to start to slow down from that point versus from where you could've started it where you were doing well." Vivian bemoaned a similar attitude among some of her diabetes patients. She believed that a perceived lack of disease-associated pain

forced patients to sometimes deny the presence of diabetes, even when other indicators verified its presence. She vexed, “Diabetes doesn’t hurt. It’s easy to ignore it. It’s not like people walking around and going, ‘My left upper quadrant’s hurting…It must be the sugars out of control.’ If that were the problem, everybody would take care of it.”

A loss of verbal communication skills was another example of an impactful disease side effect that was common among patients who suffered from a terminal neurodegenerative disease. Though patients lost the ability to speak as a result of the condition, they still maintained full cognitive functions. This was referred to as the bulbar phase of the disease and could occur at any time during the disease timeline. Since the educators interacted with patients monthly over the course of a year, it proved to be highly problematic, especially as many of their monthly engagements were delivered telephonically. Evelyn summarized it this way, “But the nonverbal thing is pretty big and is pretty frequent and it’s a big issue with the [neurodegenerative disease] population.” Penny explained that when patients would reach the bulbar phase, she would shift her verbal communication strategies by engaging more with the patient’s caregiver. She emphasized that this presented a new set of issues in that caregivers sometimes had limited availability. Even more troubling though was that she felt that by shifting focus to the caregiver, she was degrading the relationship she established with the patient. She put it this way, “Communication is very important. It does impact it a lot…when they’re bulbar onset and they can’t talk, I always reach out for a caregiver. But then again, that limits my connection with the patient.”

Treatment side effects. In addition to side effects caused by the disease, side effects of treatments were also an influencing factor in the educator-patient

communication dynamic. Educators found that treatment side effects can have a direct impact on their ability to engage with patients because they may curtail or degrade conversations. Lois pointed out how a medication's lack of efficacy, which the FDA recognizes as an adverse event, will frequently discourage patients from continuing in the multi-touchpoint telephonic program she supports. She lamented, "Sometimes I think they don't pick up the phone if they feel like the product isn't working, and they don't want to tell me that. Or they're just discouraged, and they don't wanna talk about it." Sadly, even when patients have not yet experienced a side effect with a medication, prior experiences can still create communication barriers. For instance, Iris described a situation in which a patient's experience of side effects from previous medications dissuaded that individual from actively engaging with her and from being adherent to her medication. She explained, "[The patient] told me she had side effects with every single drug…She wasn't going to take the drug while I was there…she just couldn't move past her psychological knowledge that she was going to have side effects to this drug."

A patient's disclosure of a pregnancy, or desire to become pregnant, while taking the medication is another situation that can change the dynamic of how an educator may engage with a patient in a discussion about side effects. Xoe, a diabetes educator, explained that if a pregnancy is unknown prior to the start of engagement, but is disclosed during it, educators are ethically and morally obligated to take appropriate action. This would include reviewing the prescribing information section on the use of the medication by pregnant women as well informing the patient's physician. She stated, "And all of a sudden they tell you they are [pregnant], then I think we're morally and ethically

obligated to stop and say whatever the verbiage we use is, "You need to discuss this with your physician.'"

Cora, a nurse practitioner with pharmaceutical education experience in many therapeutic areas, explained that even when a pregnant woman is made aware of a medication's risks and decides to still move forward, communication is impacted. She shared, "…[pregnancy] is pretty overwhelming. A lot of tears rolled down cheeks, but you just had to continue to hold their hand, build that trust, and explain to them [injections are] helping the baby, [they're] going to grow a healthy-sized baby." Cora later went on to explain that, while pregnancy can be a catalyst for anxiety, it can also prove to be a motivational factor for some patients. She described how some pregnant patients are more easily coached to self-management behaviors as they view doing so to be beneficial for the baby. She stated, "You find that thing that's going to motivate them…Especially for pregnant women, the majority of them, that one is an easier sell because they will do whatever they have to do to take care of that baby."

Disease-related comorbidities and disabilities. The presence of disease comorbidities or pre-existing physical or developmental disabilities frequently presented communication challenges for clinical educators. Often, these conditions were unknown to the educator prior to a scheduled engagement, thereby forcing them to react and adapt quickly.

Comorbidities. Diabetes educators were quick to note the impact of comorbid conditions when providing education or engaging patients in conversations about self-care behaviors. Hanna explained that, while her role as a CDE was always to address the primary disease, she often had to take into consideration conditions like hypertension and

obesity and adjust her information delivery appropriately. She noted, "There was always looking at different disease comorbidities, such as hypertension, weight loss…Information that had to be shared with [patients] for devices…it was always a component that something else a patient would present with that had to be dealt with." Vivian, also a diabetes educator, expanded on Hanna's notion as she reflected on how she would adjust her interaction for a patient recovering from a stroke. In that instance, she had to account for mobility and dexterity issues. She expressed,

> Having to come up for the diabetic population, with some exercise regimen that they can do after they had a stroke, rather than just say, "Go and walk 15 minutes every day," and you're in a wheelchair. Yeah, adjusting whatever recommendations are made or how, what utensils and gadgets we used based on what limitations they had.

Physical comorbidities were not the only additional health issues with which educators had to contend. The stress and anxiety associated with patients' diseases would often give rise to mental health comorbidities that could exacerbate the primary disease. Martin, a nurse practitioner and diabetes educator, believed that a comorbid condition like depression could severely impact a patient's ability to self-manage their diabetes, particularly if it involved the use of a complex insulin pump. He expressed such a sentiment in the following way, "It's like insulin pumps. Some people think insulin pumps is an automatic fix-all. Well then, you've got a patient that is depressed, and not with it. It's, 'You know, I'm not sure you're ready for an insulin pump.'"

Lois, an educator who supported patients with autoimmune conditions like Crohn's disease, reflected on the way stress could serve as a flare-triggering factor for

that disease. She shared that a frequent self-management strategy she used was to engage patients in a conversation about their perceived level of stress. This gave her insight to the patient's lifestyle and allowed her to focus her engagements on stress management tactics. She stated, "[Patients] may not realize the stress they're under until they start talking and you say, "Well, that must be very stressful." And then they realize, "Well yeah, I guess it is stressful." Sometimes they just think that's their everyday life."

Physical and developmental disabilities. Separate from comorbid conditions are physical and developmental disabilities that sometime function like comorbidities in that they require the educator to adjust their communication dynamics with patients. Many of the educators offered examples or shared stories of experiences in which they have adapted their educational engagement, sometimes without warning, because of a disability. Martin discussed one such example, "There's physical barriers. Went in one morning to teach insulin to a guy who had lost his right arm and had a prosthesis. I had not been alerted to that. It's, like 'Okay. How am I gonna deal with this?'"

Felicia, an osteoporosis educator whose medication was also administered via self-injection, shared similar examples of needing to adapt to physical disabilities such as visual impairments or muscle weakness in the hand caused by stroke or other diseases. She stated, "The medication, even with glasses, or they have to take their glasses off to be able to see it up close. Some other women will have weakness in one hand…So, it's just kind of working through little things like that." Xoe, a diabetes educator, noted that disabilities like vision or dexterity issues were sometimes not accounted for by the prescribing physician. She shared how she has advocated on behalf of a patient to both the physician and the insurance provider to get an appropriate insulin delivery device.

She explained, "…when somebody was prescribed a medication and they simply could not mechanically, technically do it. You go… 'Doc, he can't do this. He can't see well enough. We need to get him a pen [injector] so he can hear it.'"

Visual and dexterity issues were the most mentioned disabilities noted by educators. However, Martin provided an amusing anecdote of a hearing disability that exemplified the way clinical educators must often think on their feet to accommodate a patient's communication limitations. He recounted,

> Whenever I worked with the inhaled insulin, they'd have to do a breathing test…They had to blow through this device to determine if they could inhale the insulin well enough. This drug rep calls me to teach this patient. I get there to realize the patient was deaf. I'm like, "Okay. Well, we have to do this breathing test." …And I sat there making all these motions, sucking in, and blowing out with my hands. The rep and the doctor literally were in the hallway rolling…I showed the patient the device, and hand it to him. He blows the insulin out. I said, "No, no." Then I start sucking up again and they're again rolling…Then I look, and I say, "Is there a family member here with him?" "Oh yeah, his mom's with him." They bring her in, and I'm showing her. I go through the whole process, she looks at me and says, "Sir, I'm not gonna be able to remember this. I've had a stroke." I said, "Do you have someone that drove y'all?" "Yeah. My son's ex-wife's here." I said, "Get her in here. I don't care who she is or how long she's been out of the family, bring her back."

While many educators noted examples of adapting to physical disabilities, Hanna, a diabetes educator, had experience working with patients with developmental

disabilities. She shared some of the key considerations and tactics she would use when engaging those patients. She explained, "With someone with developmental disabilities…each step that you had to go through had to be practiced and repeated multiple times before moving on. With the same goal in mind, the timeframe in which it was to be accomplished was greatly extended."

Treatment administration modalities. All twenty-six clinical educators had extensive experience training patients how to self-administer medications via parenteral methods such as injection, infusion, or inhalation. In fact, most of the products the educators represented were large-molecule biologics that could not be manufactured for oral delivery. The most common administration method among the group was self-injection, usually through a pre-measured autoinjector or injection "pen", though some educators also trained patients to inject via a vial and syringe. For medications that required intravenous (IV) infusion, educators would typically just provide information about the drug during a formal training session. The actual administration would be performed later by a healthcare provider in a physician's office or infusion center. A few of the educators trained patients to self-administer sub-cutaneous (SQ) infusion medications, a more involved process than self-injection as it required multiple steps and pieces. According to the educators, these administration methods presented a degree of complexity beyond what they were accustomed to with oral medications. Not surprisingly, that complexity would give rise to barriers that impacted educators' communication.

Injecting or infusing biologic medications requires numerous steps for both preparation and delivery. They often involve multiple component pieces and supplies and

can include devices that look complex or fragile. Even the autoinjectors, which are frequently marketed as easier-to-use alternatives to traditional syringes, were perplexing to some patients. Many autoinjectors, such as those used for insulin delivery, come from the pharmacy preloaded with a multi-day supply of the medication. Those autoinjectors include a dosage mechanism, such as a dial, that allows the user to adjust the amount of medication delivered with each injection. As Tabitha, an educator who trained patients on both injectable diabetes and osteoporosis medication pointed out, this was problematic to many of her older patients with visual and dexterity limitations or who feared what would happen if they administered the wrong dose. She shared, "I probably did a thousand [osteoporosis medication] trainings, and same with diabetes. People are so frightened of, 'Oh my gosh, you mean I have to change the amount that I take every time and what if I do it wrong?'"

Lois, an educator who trained patients how to use a syringe for a medication that treated multiple chronic autoimmune disorders, often had to address concerns about her drug not being available as an autoinjector. She would draw from personal experience to explain why a syringe could sometimes be preferable to an injection pen. She stated, "I could talk about an injector pen, how it might sting with the injection…As opposed to a syringe…I could use my past experience and education to tell them they may end up liking it because it may not do this."

Janelle highlighted that some of the administration devices for the rare disease medications on which she trained were more complex than those for a common disease like diabetes. She remarked that she therefore had more talking points and checkpoints to review. She clarified, "Depending on which injectable, it's not just like a simple...you

know, ‘diabetes: click, click, click, inject, go.’ Some things are gonna have a little bit more talking points to it and a little bit more check points to it.” Evelyn, who trained on injectable medications for multiple conditions, explained how she now never makes assumptions about an individual’s ability to easily master the steps for self-administering a medication, particularly if it involves a complex device. She reflected on the difficulty a physician, who was her patient, had in assembling the injection device on which she was training and the implications for those without medical training. She noted, “[The patient] did get it, but all I was thinking of...and this was somebody that worked in critical care with a lot of devices…Just because somebody’s educational background indicates that they should know about it, they might not.”

In some instances, the mechanical complexity of self-injecting was less of concern to educators than the computational complexity that was required. Quinn, an educator for self-injectable diabetes and osteoporosis medications, hypothesized that the reason one of her diabetes medications struggled in the marketplace was because it required patients to calculate, or titrate, their dose before administering. She felt titration was difficult for her patients because the dosage could change from day to day based on factors such as a blood glucose reading. She lamented, “It was a powdered insulin that was titrated. That was really hard. Especially when they’re older to explain how to titrate medication. They want to know exactly what am I supposed to take at what time and how much.” Xoe shared similar thoughts about a powered insulin product on which she trained that needed to be mixed before injecting. In fact, she explained how she would encourage patients to delay picking up their prescription until after they were trained lest the task be too difficult, and they would end up paying for medication they couldn’t use.

She shared, “There were some people who could not do it…We would tell them, ‘Don’t fill your prescription. Come let us teach you how to do it’…We wanted to make sure they could do it before they spent money on a prescription.”

Like political/legal context factors, the disease and treatment context factors served not just to influence patient/educator communication, but also to constrain it. In many instances, these factors functioned as barriers that impeded educators’ ability to engage patients in the types of communication that could provoke behavior change. In turn, patients’ ability to better self-manage their disease and treatments were at risk. The next theme examines the communication strategies clinical educators used to address these factors and thereby overcome such barriers.

Using Communication Strategies to Address Ecological Factors

Theme 4: Educators employed communication strategies to better navigate within the political/legal and disease and treatment context ecological factors.

Pharmaceutical-sponsored clinical educators spoke frequently of the importance of quickly establishing and maintaining trust in their patient relationships. Doing so was viewed as a necessary precursor for working within the ecological factors that frequently functioned as barriers to disease management. Educators also understood that the components of the disease and treatment context needed to be accommodated as part of any communication strategy they deployed. Hence, educators would frequently try to make a personal connection with the patient in hopes of “meeting the patient where they are at”. When faced with political/legal barriers, a common strategy for addressing the staying on-label and fair/balance presentation factors was “deferring”—redirecting patient questions or concerns they were not allowed to answer, back to the patient’s HCP.

Though educators noted that deferring could sometimes frustrate patients, they learned that they could leverage the trust they had built in their relationship to help abate that frustration. The educators would employ verbal tactics during deferring, beyond a simple "You'll need to talk to your doctor about that", that kept the conversation opened and the patient engaged. Lastly, as the communication medium could cause barriers to arise, particularly in the instance of telephonic engagements, educators developed linguistic skills that proved useful to navigate such barriers. This section explores the strategies educators would use to address some of the barriers posed by the political/legal and disease and treatment context factors. These include pragmatic "stick to the rules" approaches, as well as conversational and carefully worded linguistic nuances that could sustain trust while maintaining compliance.

Communication strategies to address political/legal context factors. Clinical educators and their patients needed to traverse political/legal context factors that were manifested in government and industry-imposed compliance regulations. Specifically, the regulatory factors of staying on-label, fair-balance presentation, and adverse event reporting were the main factors within that context that were examined in this study. However, other compliance-related concerns were also discussed by participants. Though political/legal context factors did present challenges and barriers to patient and clinical educator interpersonal engagement, the educators had established a range of communication strategies to address them.

Some of the educators expressed a pragmatic sentiment that navigating compliance regulations was best accomplished by just "sticking to the rules," particularly when it was related to using company-provided educational language and materials.

Unlike educators who had expressed reluctance to never deviate from program directives, these educators thought the best course of action was strict adherence. Gabi, an educator who trained patients on medications for osteoporosis and chronic autoimmune conditions articulated this view when she said, "What you can do is stick to the package insert and training material and point out these are possible side effects and if they have questions, we refer them to their physician or pharmacy or back to the medical department." Sophie, a diabetes educator, reinforced the same concepts as Gabi when she stated, "We would do really everything by the book…And then there were some things we could hand people, some [pharmaceutical company]-provided care sheets or educational material. Those things we could provide to patients. But that was it." For most educators, this strategy of sticking to the rules was rooted in a fear of non-compliance repercussions. That belief was evident in the way educators articulated their disagreement with some compliance regulations in principle, but still demonstrated compliant communication and actions in order to avoid potential legal or disciplinary actions. Hanna, a diabetes and osteoporosis educator, articulated this very notion when discussing why she would not address off-label questions. She stated, "It's hard to walk both lines, because you want to be able to say something, but it's not within your scope of practice. While you still have to know that your license allows you to do this, you carry liability." Fear of credential loss was also a motivating factor for Quinn, an educator who trained patients with diabetes, osteoporosis, and autoimmune conditions, who noted, "So I keep their stuff all private and I'm very compliant because I don't want to get in trouble. And I don't want to lose my nursing license. That would not be good."

Regardless of liability threats, most educators found creative ways to navigate within the compliance factors of staying on-label, fair-balance presentation, and adverse event reporting, while avoiding regulatory violations. The next three sections explore some of the popular strategies and tactics educators used to accomplish this feat.

Strategies for staying on-label. While sticking to the rules was the pragmatic and default approach many educators strove for to ensure compliant communication and content presentation, it was also something that seemed easier said than done. Educators were quick to point out that patients could be assertive and persistent in their search for answers, often to questions to which educators were unable to compliantly reply. Janelle, who provided training on products for patients with rare diseases, was an educator who spoke at length about this dilemma. She shared the following example of how she would defer a patient back to their physician while also providing a rationale for why she was unable to fully address their concern.

> The way I frame it too, if they're having these side effects, they're like, "What should I do?" And I say, "Unfortunately, in our clinical trials when our patients did report headache or nausea or itching, we didn't give them any medication before, during, or after their infusions because we didn't want to suppress this data…" But I say, "Your doctor can recommend adjustments to your plan of care surrounding your infusion to potentially mitigate those side effects. Did you ask your doctor what they could do about these headaches or whatever?" "Oh, no, I didn't." "You need to go back and ask them, because if you're not talking to them, they don't know this is occurring and they can't adjust your infusion plan orders and your plan of care."

Janelle went on to explain that another reason she believes it's important to stay compliant with her conversations, particularly when she is providing telephonic education, is to avoid creating disruptions or conflicts with a patient's HCP. She felt that in those circumstances in which she creates confusion, her actions could reflect badly on her pharmaceutical employer. She stated, "What doctor wants to hear their patient say, 'Some lady on an 800-number told me this.' That doesn't bode well if you are with a pharmaceutical company. As long as I stay on PI, that's a good cover."

Felicia, an osteoporosis educator, also reflected on the nature of compliant communication and physician relationships. However, as she pointed out, in some instances, the healthcare provider can create the confusion when they provide patients with information or instructions that conflict with the product label. For instance, in one example, Felicia explained how a physician told a female patient to inject the medication in her thigh instead of the label-prescribed method of injecting in the stomach area. Felicia understood that the physician may have had a therapeutic reason for changing the injection location for that patient, however, she was not allowed to deviate from the label in her presentation. She was able to work around the discrepancy through body language gestures and by verbally over-emphasizing the phrases "I must tell you" and "why it is pictured here." These tactics served as visual and linguistic signals to the patient to continue following the physician's instructions even though Felicia was stating and presenting something different. This is how she described it.

> I follow the deck and I followed the handout, the leave behind material… sometimes it's funny, physicians will give directions to the patients that are not compliant to what we are teaching. Like the injection site...To be compliant, you

> inject in the belly. The physician told the patient your thighs, and I said, "No, *I must tell you*, you have to inject in your belly, which is *why it is pictured here* on our information."

Felicia continued by providing another example in which physicians would correctly instruct patients that they did not need to refrigerate the medication once it was opened. However, the physicians often did not take into consideration that many of her south Florida patients did not always use their air conditioning. Hence, the temperature in their homes would exceed the allowable room temperature storage requirements noted in the product label. Once again, she would use signaling body language and verbally emphasis key phrases such as "as stated right here" to clarify the physician's instructions. She explained, "They're like, 'My doctor said, I don't have to refrigerate it,' as I'm in their home sweating. I'll say, 'That's true. However, if it's warmer than 77 degrees, *as stated right here*, you need to keep it in the fridge.'"

Resources such as scripts, presentation outlines, discussion guides, and frequently asked question (FAQ) documents provided the guidance for delivery of compliant and on-label programs. However, patients would still continue to ask questions beyond the scope of those materials. Fortunately, educators employed many different communication strategies to contend with these instances when they were unable to address a question or concern. Most educators expressed that it was important to explain to patients *why* they were unable to address off-label questions. For instance, Penny, an educator for a terminal neurodegenerative condition, would point out to patients that she was only allowed to speak to the information in the package insert (i.e. label). She said, "Well, I just redirect them to the package insert and say that... 'I cannot talk about that

information because it's not in the package insert and it wasn't within the study guideline.'" Deandra, an educator for autoimmune conditions, shared a similar refrain though she placed the onus on her company while also noting that her patients tended to accept her reasoning. She stated, "…I'm very honest. I say, 'I'd like to answer that question…But in my present position, my employer won't let me.' They respect that…So they usually don't have a problem with that." Martin, a diabetes educator, articulated that patients were generally accepting of the compliance restriction when provided a rationale, though he was quick to point out that he avoided the use of the term "off-label". He felt some patients would not comprehend its meaning. He shared this response about how he addressed a patient's question regarding a different product than the one he represented. "I don't use the term 'off-label'. [Patients] don't understand. I'd say, 'This medicine isn't meant to be used by this person. While they may get some benefit, it's not recommended.' Whenever you say it that way, most people get it." Reba, a diabetes educator, explained that she would address that situation by reminding the patient of her limitation to speak only to her product and deferring the choice to the physician's therapeutic assessment. She said, "I'd say, 'I'm here because I'm being sponsored by this company, and I can't discuss other medications." …Although [patients] might say, "Well I take [insulin] instead of [another insulin].' I'd say, 'That's a choice that you and your physician make.'"

Olivia, an educator for a product for a terminal neurodegenerative disease, took a proactive approach to handling off-label questions. She explained that she would set expectations at the beginning of her patient engagements regarding the scope of questions she could address. When patients would start to get "out into the weeds" with off-label

questions, she would remind them of the expectations she set at the start and refer them back to their physician. She felt this made those situations easier on both her and her patients. She described it this way, "I tell them, 'We're nurses, but we're never going to give you any medical advice.' I set that expectation up front. If they start getting out in the weeds, I'll say, "Remember when we talked about this? I need to send you back.'"

While most educators discussed the importance of providing a rationale for their inability to address off-label questions or concerns, that tactic was typically just a first step. Educators would often follow with additional conversational or linguistic strategies they found effective for maintaining their interpersonal connection with patients. For instance, Deandra, a chronic autoimmune disease educator, believed a good strategy was to seek out the motivation for a question. Doing so provided her additional insight into the patient's disease experience or to the barriers that could be impeding comprehension. She described it this way,

> First, acknowledge their concern. They're obviously asking that for a reason, either they experienced it, they heard it from somebody or...You say, "Hey, can you tell me what's going on? Why is it that you're asking that question? I realize I can't answer it fully but maybe I should understand a little better why you're asking it and perhaps I can address the motivation behind it" … But, hopefully and asking a little bit more about their motivation or where that question is coming from, I can still have a conversation with them and perhaps talk about something else that's going on in the background that they don't understand, something about their disease process or something like that.

Bonnie, an educator for multiple chronic conditions, felt an effective strategy was to encouraged patients to write down the questions she was unable to address and then share them with their HCP. She believed this helped reinforce the validity of their question and averted an impression that she was being dismissive. She stated, "A lot of times I start a list for their provider or encourage them to keep a general list of questions…But I'll give them another way to get that information or validate that it is an important question or concept." According to Cora, an educator for numerous chronic conditions, this tactic worked well in her multiple-engagement telephonic programs in which patients were sent a resource guide ahead of time. At the end of the first call, she encouraged patients to write down questions in the back of that guide they would like answered the next time she connected with them on the phone. She felt that this action not only better prepared patients for their program, it helped nurture the sort of trust that improved care. She stated, "We tell them up front, 'We're going to send you information. When you read through it, write all your questions down so when your educator calls…you can go through and get them answered.' Right away, that builds the trusting relationship."

Lois, another telephonic educator, supported a medication indicated for multiple common chronic autoimmune diseases for which there were competitor products. As she explained, some of these other medications were in the same drug class as her medication as they had comparable pharmacological mechanisms of action, meaning they worked in the body in a similar way. She highlighted how she would tell patients that, though she could not speak to the specifics of competing products, she was able to talk about the drug class. She found this strategy helpful when patients would ask comparative

questions related to medications' side effects. She stated, "I say, 'That product is in the same pharmaceutical drug class as my product, but they're made differently and act differently. I can't speak to that product, but I can tell you that this is what this product does.'"

Another option educators could utilize to handle off-label questions was to refer patients to the company's medical information phoneline. This is a telephonic support service staffed by physicians, pharmacists, or advanced practice clinicians who are authorized by the companies to provide detailed scientific and therapeutic product information to HCPs and, in some cases, to patients. These support lines are generally not held to the same stringent compliance regulations as the marketing divisions of the company. Gabi, an educator for common chronic autoimmune diseases, shared she would sometimes use this strategy. She stated, "I'll just say I can't discuss that, that's something not my role. I don't make it like '…this company won't let me'… I'll say, 'But here's the number to our medical department'. I just refer them back to medical."

Referring patients forward to a companies' medical department was a noted option, though educators spoke more frequently of deferring patients back to their HCP to answer off-label questions. This strategy was also encouraged by the pharmaceutical companies. However, educators recognized that there was a risk of upsetting or annoying patients by deferring them, especially as patients tended to view the educator role as that of an information provider. Hence, they described the deferring process as a delicate situation that required communication nuancing, or as Cora, a telephonic educator for numerous products, described it, "tap dancing". She put it this way, "You can always refer them back to their healthcare provider…I think most of the time people understand.

But every once in a while you will have a disgruntled patient…You have to learn a little bit of tap dancing at times." Whitney, a diabetes and osteoporosis product educator, used a similarly analogy by referring to the deferring process as "steering". She stated, "The biggest trouble I had with patients is, 'What do I do about dosing, or if I want to change this?' or more like clinical kind of things…You just have to steer them back to the family doctor."

Educators described multiple communication techniques they used for easing the deferring process. One such strategy was to remind patients that their physicians possessed the requisite scientific knowledge about the drug to properly address certain questions. Felicia, an osteoporosis product educator, explained how she used that approach in the following way, "Questions like that I've just refer back to the physician. 'Your physician understands all the molecular capabilities of this medication that I honestly can't explain to you. But he's been educated and that's why he's ordering this over anything else.'" Ursula, a diabetes product educator, described how she used similar language in instances in which patients would ask her questions about other drugs in the same medication class as the one on which she trained. She shared, "If somebody was on a GLP1, there's like five companies that make them, if somebody asked about another brand, I'd refer back to the physician, '[He] had this in mind for you and this is why he chose this one.'"

In addition to reminding patients of their physicians' scientific expertise regarding the medication's mechanism of action, educators would also reiterate that the doctors possessed a detailed understanding of patients' specific medical histories. Those histories influenced the decisions the doctors would make about prescribed medications. Quinn, a

diabetes educator, shared the following response she would give patients, “You need to call your doctor and I'm sure the nurse or doctor would love to answer this for you. Or could answer it for you. I really don't know the depths of what's going on and can't answer that.” Janelle, an educator on multiple products for patients with rare diseases, reinforced this same message by also informing the patient of the potential harm she could cause because she did not know patients’ medical histories. She felt it was important to reframe the message so that patients understood that her rationale for deferring was for their protection. She said, “Sometimes they'll press me on it and I'm like, ‘If I told you three medications to take, but you were allergic to two of the three of them, am I helping you at all by that? Because I don't have your medical chart.’” Later in her interview, she discussed how using this same tactic for off-label information requests worked well with her telephonic patients. She shared this sample response as an example, “Unfortunately, I can't respond to that because I don't have your medical chart’...And so [they understand], ‘Oh, she's not doing it because she doesn't want to talk to me, she legit doesn't have enough information to make that decision.’”

In some instances, educators would go beyond just deferring to also take on intermediary responsibilities between the patients and their physicians. Penny, an educator who engaged with terminal neurodegenerative disease patients on a monthly basis, was allowed by her pharmaceutical sponsor to periodically contact her patients’ HCPs to provide progress updates. This was a unique feature of her program and not typical of most others. She explained that when she would defer an off-label question to the physician, she would also offer to contact the physician’s office ahead of time to let them know the patient would be calling with a concern. She felt this helped reinforce her

commitment to the patient's needs considering her limitation to address their question. She shared this response she gave patients as an example, "It seems like a very important question…What I can do is also connect with the office and let them know, if you'd like me to, that you're gonna call and you do have a question."

Deandra, an educator who often trained her patients in rooms at their physicians' offices, took a slightly different intermediary approach. She felt that sometimes patients were intimidated to ask their doctors questions. Therefore, she would offer to pull the physician into the room on the spot so she could assist the patient in asking the question. She described it this way, "I'll say, 'Maybe we can pull the doctor in here and have you pose that question to him,' because sometimes patients are a little bit afraid to question the physicians…The physician's like 'the all-knowing' and you never question him."

Strategies for fair-balance presentation. Fair balance presentation is the requirement that pharmaceutical companies balance information about a medication's benefits with equal emphasis on its risks and side effects. Bonnie, a telephonic educator for many different types of products, summarized it this way, "You want to make sure that if you say something that's positive about a medication, that it's explained in context, but you also share what risks there may be and what potential side effects there could be." The pharmaceutical companies typically relied on program resources such as scripts, presentation decks and guides, and other support materials used by the educators as the main strategy for ensuring compliance with this regulation. Educators also understood that there were potential liability consequences were they not to comply with those guidelines. However, a few educators thought compliance with this regulation was also a moral obligation and therefore reflected that belief in their communication with

patients. For instance, Deandra, believed that fair-balance presentation ensured a perception of honesty and promoted a stronger relationship and rapport with patients. She noted, "Honesty is the best policy. Don't sugar coat too much, tell them what it is. They may not like it, but they will respect you and eventually come back to you and say, 'You know, you were right.'" Deandra was not the only educator to use the phrase "not sugar-coating" to describe how she strove to maintain trust with patients. Lois, a telephonic educator for a product that treats multiple chronic autoimmune conditions, expressed the same sentiment. She stated, "And I'm doing what I'm supposed to be doing, and I'm not sugar-coating anything when I read the safety information to them. So, that is a way to earn trust. They don't feel like I'm selling something to them."

Strategies for adverse event reporting. When patients share with educators an adverse event (AE) or side effect they have experienced, the educators are required to document and report it to the pharmaceutical company. The company, in turn, reports all AEs to the FDA who tracks them. While AEs are typically not desired responses to a medication, many of them are common or expected reactions that do not affect the efficacy of the medication or cause long-term harm. Educators explained that part of their responsibility when receiving AEs is to simultaneously impress upon patients the importance of sharing that information with their physician while also not unduly alarming them. Reba, a diabetes product educator, summarized this approach in the following way, "I would probably say 'With any medication, even over the counter medicines like aspirin, there can be undesirable side effects…Certainly, if you have symptoms, you need to be discussing those with your physician or your care provider.'" Cora, an educator for many different products and disease states, noted how an adverse

event could even present an opportunity for a teachable moment that helped the patient understand more about their disease. She talked about an example of a diabetes medication in the following way, “We're well-trained in being able to recognize and capture [AEs]. I know for some [patients], they've had complications that they had no idea were even related to the medication or it was a sign their blood sugars were off kilter.” Yvonne, a diabetes educator, also thought there was value in using a reported AE to further educate a patient, particularly on the process by which a physician determines how and why to prescribe a medication. She provided the following sample explanation she gives to patients to iterate this point. She said, “When a doctor makes a decision to put you on a product, they’re weighing the individual's indications, the contraindications, and with knowledge of the patient's medical history, makes a decision, this would be the most favorable thing for this patient.”

Janelle, a telephonic educator for patients with rare diseases, pointed out how an AE could be troublesome for a patient if it was not a common side effect noted in the product label. When this happened, she would educate patients on how side effects are captured during clinical trials and why it is difficult to document all of them during the product’s research phase. She provided the following example to highlight her approach, “If something is not what the side effect profile said was in clinical trials, I say, ‘You have other diagnoses, other medications that could be potentially causing an issue that we didn't capture in our clinical trials,’…Give them extra information.”

When educators explained their communications strategies for handling reported side effects, they often provided a description of the way they instructed patients to share the AE information with their doctor. Felicia, an osteoporosis educator, stated such in the

following manner, “What I'll tell them is that I report it…and then I tell them, ‘You've got to call your doctor, he has to be aware of this. Thank you for telling me, but you've got to let him know as well.’” Gabi felt that it was important for patients to follow-up with their physicians regarding an AE as doing so promoted medication adherence behaviors. She used the example of the osteoporosis product on which she trained to illustrate this belief. She said, “So making sure they're aware of those side effects...to expect them. So, they don’t stop taking their medication as soon as they have one…that it's important to stay in contact with their doctor because those side effects reduce over time.”

Much like the deferral strategy for an off-label question, educators would sometimes serve as intermediaries by assisting patients in the sharing of an AE with their physician. Yvonne, who often trained patients in the physician office, described how she would use that location to her benefit when patients presented a side effect. She stated, “The offices I worked in, the doctors were usually right there. And they would stick their head in and I would say, ‘Mrs. Jones has an issue with such and such. Do you have a moment that you can talk?’”

Telephonic educators contended with AEs as well, though they had to adjust their communication tactics to fit the modality. Janelle described strategies she would use when confronted by an AE to which she was unable to visually inspect. Like other clinical educators, she strove to assess and address the AE within the limitations of her compliance capabilities and would then defer patients back to their HCP for appropriate care. She provided the following example to illustrate how she would handle a patient who had an injection site reaction. She explained, “I ask them clinical questions, but at

the end I always refer back... 'You need to let your doctor know because I can't see it. If it's hot, red, inflamed and hard, we didn't see that in the clinical trials.'" Janelle even shared that if she believed an AE to be severe enough, based on the patient's description, she could recommend that the patient seek emergency assistance. She said, "I'll ask questions to see the severity. Do you need to call the doctor tomorrow or call today? Do you need to go to the ER in the next 30 minutes? I can say, 'You need to seek emergency assistance.'"

Lastly, educators came to understand that side effects could sometimes be severe or onerous enough that patients would decide to discontinue the medication. Iris, an educator for multiple common chronic disease conditions, explained that, in those instances, it was important to respect the patient's decision and not pressure them to continue with the medication. She said, "When a patient tells me, 'I don't want to take this drug anymore.' That's [their] choice. I respect that…I explain to them about AEs and wish them good luck. 'Hope that you're able to find something that works for you.'"

Communication strategies for disease and treatment context factors. Like the political/legal context, disease and treatment factors produced a range of barriers that directly influenced patients' willingness and ability to engage in interpersonal communication with clinical educators. Fortunately, the clinical educators mastered many types of communication strategies for addressing those factors. One technique that educators relied on was engaging the patient in a conversation that centered on a personal connection. For instance, Yvonne, a diabetes educator, explained how she would try to relate the patient's disease experience to a topic like auto mechanics or electronics if she knew those were relevant to her patient. She described it this way, "If they work on cars,

I can relate healthcare to an engine...technology is a little bit more tricky…but it's just electricity meeting with a number of obstacles…When you start talking to people about that, you can talk to those people." Vivian also stressed the importance of making a personal connection that centered on a partnership between her and the patient. She would use the pronoun "we" to emphasize the joint nature of creating a disease self-management plan. She expressed it this way,

> If I walk in, I tell them, "I'm [Vivian]. I work with the diabetes team. We need to talk, because your sugars are up, way out of control." Then that's it. I'm already out the door. Nobody's listening. But I found that if I go in and say, "Your doctors are concerned about your sugars and wanted us to get together and see what we can do to make things better. Tell me what you're doing at home. How's it working?" Then all of a sudden, they open up…so just establishing this little factor of I'm willing to listen to you. Tell me what you're doing and why is it working or not working, and then we develop a plan.

Another part of establishing that personal connection according to Evelyn, an educator who treated patients with a terminal neurodegenerative condition, was helping them understand the uniqueness of their experience. She discussed how she sometimes discouraged patients from focusing on how others handled their disease because it drew energy away from their own battle. She clarified, "[Patients will] say, 'Well, how are other people doing on it?'…I always go back to 'Everybody's disease process is different, everybody's response to the medication is different, so talking about other people isn't important. What's important is talking about you.'"

While educators mostly referenced communication strategies they used with patients at the start, or at transitions points, of the disease journey, Janelle highlighted the importance of appropriately engaging seasoned travelers. She worked with patients who frequently changed therapies, so she approached conversations in a way that avoided assumptions about experience or comprehension. She stated, "I don't want to jump in with someone who's already had seven injectables for psoriasis…and they're like, 'I've been doing this for eight years,'…I'm not gonna jump in and start yammering; I care more about meeting them where they're at." Later in her interview, Janelle also reflected on how the nature of the diseases and medications to which she treated occasionally forced her to take a more hard-nosed approach in her conversations. She provided the example of how she mandated patients complete their first injection of an anticoagulant while she was present to avoid serious and life-threatening outcomes that could result from non-adherence. She described it this way,

> It could be life or death if they didn't give themselves these shots…So, explaining the severity of if they didn't do it...you can't do that in a nice way. Sometimes you had to get a little bit firmer with some patients who kind of wanted to play it off like, "Oh, I'll do it when I get home." "No, you won't. If you won't do it here, you won't do it at home once no one's staring you down."

When addressing barriers related to injection and infusion administration modalities, multiple educators discussed the importance of correcting injection misconceptions, particularly about such as things as the needle's size and associated degree of pain. Deandra described the language and process she would use to walk a patient through their first injection. Her first step was to understand any barriers while

also providing verbal reassurance. She explained it this way, "Perhaps they think it's some two-inch long needle. So, show them that it's really small…Assure them I will be there to do this each and every time until they're comfortable with it. 'I will help you with this.'" Sophie shared a similar understanding and described her preferred tactic of doing an injection demonstration to address the barrier. She stated, "It is not uncommon for myself to just do a dry injection, show them what it is like to do with a sterile syringe…if they can see somebody do it and actually have them do…they can start to learn."

Telephonic educators also used communication workarounds for handling similar technical issues that would arise related to proper self-injection or self-infusion techniques. One tactic was to create a visual analogy to which a patient could more easily relate. For instance, Lois provided an example of the way she would verbally assist a patient needing assistance with the proper way to hold a syringe. She shared, "Like for instance, how to hold a syringe. I'll say, 'Well hold it like you're getting ready to throw a dart, or holding a pencil', things like that. And then they'll say, 'Oh, okay, that's how you do it.'" Janelle, on the other hand, noted that she would sometimes refer a patient to the company's website while she was on the phone with them, to walk the patient through the steps of a complex self-infusion process. She explained, "If I'm not getting them, I ask… 'Do you have access to the Internet? We've got a video online that the nurse walks through the process.' So, they'll pull that up and be like, 'Oh, I was totally missing this.'"

Patient misconceptions were also pervasive barriers when discussing disease and treatment side effects. For instance, Xoe noted that many of her patients had erroneous beliefs about insulin. She explained how she often had to address a common

misperception that insulin was a therapy of last resort necessary for patients who failed to effectively manage their disease. She shared, "We tried to take the mystery out of stuff, even when we did classes, to show them that… 'Insulin isn't because you failed, it was because you had a change in your condition.' I think new education does that."

Another language strategy that educators would use was framing disease and treatment context messages in the format of a preventative measure. Felicia used this approach for her osteoporosis patients who were at risk for a fall-related fracture and were prescribed a daily self-injectable biologic that stimulated bone growth. When asked by patients why they needed to take the medication for two years, she would say to them, "Because your option is a fracture, vertebral fracture, hip fracture, and then that alters your life forever. Once you fracture your hip, you're looking at hospitalization, surgery, physical therapy, medications, it changes everything." Like Felicia, Janelle found that reframing the injection message in the context of a preventative measure was necessary for rare disease patients. In her case, those individuals were sometimes parents who were needing to administer an injection or infusion to their young child. She shared this example of how she would speak to them, "We're doing this because we want them to not have a bleed'…retooling the idea of 'I've gotta stick a needle in my kid.' 'You're doing this to help them.' Reframing that whole idea…to get them in a comfortable spot."

Martin, a Type 1 diabetes educator who worked with children, discussed other recommendations he felt were effective when speaking with parents and youth afflicted with disease. He stressed how the foundation of that communication was based on establishing trust, which included both a need for honesty as well as opportunities for children to make some decisions about their treatment. He explained it this way.

> Telling a young child, “This is not going to hurt,” is not a way to build trust. Because, we know giving insulin may hurt. We have to kind of build that trust and say, “We've got to do this.” And offer options. That's what I used to do with them. And I'd tell the parents, “Let them choose where they want the insulin injected, but it's not a question of, ‘Do you want to take this insulin?’ or ‘Do you want to check your blood sugar?’, it's ‘Which finger do you want to use?’ But yeah, trust, especially in diabetes, because this is lifelong. And if you breach that trust it could make it very difficult in the future.

Summary of Findings

Ecological factors were influential in the educator-patient communication dynamic. However, the political/legal context had the greatest communication impact for interviewed participants as it was the only one interpreted primarily in the direction of educator to patient. Industry and government-imposed compliance regulations were the most discussed political/legal context factors, particularly as they related to the factors of fair-balance presentation, staying on-label, and adverse event reporting. Unfortunately, while educators reluctantly understood the rationale for these regulations, they were still frustrated in the way they impeded communication and jeopardized patients’ comprehension of information. The inflexibility for adapting language and materials to specific patient learning needs was viewed as particularly problematic. Not surprisingly, that frustration would sometimes lead to purposeful non-compliant behaviors as educators weighed the expectations of their role against their duty to provide the best care possible to their patients.

Educators also struggled with other ethical situations that pitted their professional integrity and altruistic nature against the expectations of their role. The experiences of Antonia, Iris, and Tabitha, who engaged in purposeful non-compliant behaviors, illuminated the complex deliberations these educators faced when confronted with morally conflicting situations. However, while those three educators were most articulate in expressing their rationales for non-compliant behaviors, they were not alone in their feelings. Most educators reflected, at least in some part, of the ethical implications of their role. In many instances, educators interpretations were presented within a dual-loyalty context—situations in which they must choose between two equally deserving alternatives. The most noted type of dual-loyalty conflict was between their patient and their employer. However, educators also shared examples of conflicting loyalties of patient versus their HCP and patient versus their family.

Though the political/legal context was the only one of Street's (2003) four original contexts that was examined, it was not the sole influential domain in educator/patient interpersonal communication noted in this study. Data analysis revealed a new context that educators interpreted as being highly impactful in the way patients and educators engaged each other. The disease and treatment context included the varied components of a patient's disease experience that would frequently necessitate that educators change the way they interacted with patients. Factors that were part of this context included such things as disease type (e.g., chronic, terminal, rare), disease-related side effects, treatment-related side effects, the prevalence of comorbidities or disabilities, and drug administration modality (e.g., oral, self-injectable, self-infusion).

The role of ecological factors within the political/legal and disease and treatment contexts did more than impact *how* communication occurred between educator and patient. In many instances, those factors manifested themselves as behavioral barriers that impeded appropriate disease and treatment management. Hence, educators employed a variety of communication and behavioral-management strategies to help them and their patients navigate through those barriers. Educators also learned the value of establishing trusting relationships early in the engagement since they could leverage that rapport when faced with the limitations imposed by compliance regulations. The next chapter examines findings related to this concept of trust relationships within the context of how educators managed privacy with their patients. It explores in detail the type of confidant roles that educators take on as part of that process while also addressing how educators work to avoid breaches of trust.

Chapter 5: Findings—Communication Privacy Management (CPM) Theory

The findings for this chapter are examined within the context of Petronio's (2002) communication privacy management (CPM) theory and address the second research question: *"How do those ecological factors influence the way pharmaceutical-sponsored clinical educators establish and manage communication privacy boundaries with patients?"* As discussed in Chapter 4, the ecological influence of political/legal context factors has the potential to erode the trust that is established between clinical educators and patients during educational encounters. Yet, the ongoing success of clinical educators' networks suggests educators can retain the requisite level of trustworthiness to coach and counsel patients to effective disease self-management behaviors (eyeforpharma Ltd. & S3 Connected Health, 2018; Newmark & Blackburn, 2018). The process by which educators maintain trust and navigate within communication complexities can best be explored through the lens of CPM theory (Petronio, 2002) and its focus on the relationship between patients' disclosure of private information and educators' confidant role types.

The nature of the pharmaceutical-sponsored clinical educator role as secondary or tangential to the primary healthcare team presents a unique challenge for both the educator and the patient regarding how the patient's health information is shared and managed. For instance, educators noted that patients changed the way they sometimes confided with a clinical educator because of perceived role differences from the primary care team. Similarly, educators have provided insights regarding how they interpreted their role as a healthcare confidant in a different way than a primary care team member due to the health information limitations that are placed upon them. CPM theory is used

here to help interpret this discourse. This chapter presents evidence of how both disclosers and recipients of private information create privacy rules that help them manage that information. Specifically, the findings presented here interpret (a) how the establishment of trust is foundational to educators' ability to solicit disclosures, (b) how educators and patients established rules for managing private information, and (c) how educators were representative of three CPM theory confidant roles. The chapter is organized around three themes that represent the major findings as related to CPM theory and the second research question. Those themes are:

1. Educators believed they needed to establish and maintain trust throughout the engagement process for them to successfully solicit meaningful patient disclosures.
2. Educators managed the information disclosed to them by patients using routinized rules based on core privacy rule decision criteria as well as changing rules based on catalyst privacy rule decision criteria.
3. Educators managed multiple types of confidant roles with patients including stakeholder, deliberate, and reluctant.

Trust and Privacy

Theme 5: Educators believed they needed to establish and maintain trust throughout the engagement process for them to successfully solicit meaningful patient disclosures.

Trust is a hallmark of CPM theory. When it has been examined within the context of healthcare and medicine, the theory asserts that as a patient decides to disclose private information to a healthcare professional, such as a clinical educator, the action is predicated on the notion that the educator's professional status and credentials carries an

inherent level of trust that the information will be protected (Petronio & Sargent, 2011). Additionally, while patients' need for obtaining healthcare services is the primary motivational factor for revealing health information about themselves, patients might still perform a risk/benefit analysis about when, what, and how much to disclose to an HCP. A relationship grounded in trust, therefore, helps mitigate risk, which in turn, promotes greater comfort for disclosure (Petronio et al., 2012).

This theme examines educators' interpretations of trust and its necessity in soliciting the types of patient disclosures that help educators coach patients to successful disease self-management. This examination begins with a discussion of how educators' defined the nature of trust as it relates to privacy management behaviors. Next, educators' descriptions of how trust is established with patients is explored, followed by an explanation of how trust is strengthened and maintained throughout the engagement process. Lastly, the concept of loss of trust is explored and its impact on patients' privacy disclosures.

Defining trust. The clinical educators were unanimous in their belief that a relationship built on trust was a requisite for soliciting meaningful disclosures from patients. The way the educators interpreted or "defined" the concept of trust, however, did vary. For instance, Antonia, an educator for patients with a terminal neurodegenerative disease, felt that trust was predicated on patients feeling respected by the educators. She stated, "If I think of trust, do I trust you that you won't steal my money? Not that kind of trust. But do I trust you to treat me with respect? ...In that respect, I think it's very important." Cora, an educator for numerous medications and disease types, felt that trust was investing in the vulnerable nature of the patient status

and allowing them to feel comfortable in "exposing" their fears and concerns. She put it this way, "When you develop a trusting relationship with a patient, then they're able to really expose their inner self and all their fears and concerns, and that's where you're really able to build the bridge to help them accept the diagnosis." Reba, a diabetes educator, interpreted trust in a similar manner stating "I think [trust] plays a really important role, because especially with diabetes, people are putting their faith and trust in you to lead them in an appropriate direction. So, I feel it's extremely important." Finally, Karl, a telephonic educator for chronic autoimmune conditions, summarized succinctly its importance in the educator-patient dynamic when he stated, "Trust is everything. If you cannot develop trust, you're not going to get anywhere."

When discussing the concept of trust, many of the educators spoke of it in conjunction with the concept of "rapport," though there was often discrepancy regarding its interpretation. Some educators considered the terms to be similarly defined, or even synonyms for each other. Bonnie, a telephonic educator for multiple products that treat numerous conditions, articulated as much when she stated, "Trust is one of the most important factors, you can call it rapport or connection…and it's about [the patient], that you're truly here to help that person and not yourself and not for some other reason." Gabi, an educator for osteoporosis and chronic autoimmune condition drugs, implied a similar understanding of the synonymous nature of the two terms. She used them interchangeably while discussing their importance at the start of her patient education programs. She stated, "…that the patient has that trust in [educators] before they start the training. That's why I think it's important to...take the time to develop a relationship or a rapport with them before you start the training. So they feel comfortable."

Conversely, Hanna, a diabetes and osteoporosis educator, felt trust and rapport were distinct components of the educator-patient relationship. However, she was unsure as to which one served as the catalyst for the other. She explained, "You can't have trust without building rapport, and so I don't know which comes first, the chicken or the egg kind of thing. I mean, you have to have one to be able to have the other." Penny, an educator for patients with a terminal neurodegenerative condition, however, was clear in her understanding of the two. She believed that rapport was a precursor and requirement for the development of trust, as trust could only be earned once rapport was established. She put it this way, "If you develop rapport with them, that leads to trust over time. The most important thing is being able to connect with them immediately, so that connection and rapport building is a bridge to developing trust."

Establishing, maintaining, and losing trust. While all the educators agreed that trust was a requisite for successful interactions with patients, there were differing views regarding how patient trust was earned or established. Some educators believed that their credentials or status as a nurse automatically afforded them trust. Others believed trust was not something that was imbued, but rather needed to be worked towards. Nadine, a telephonic educator for chronic autoimmune conditions, hypothesized it was a combination of both when she explained,

> Nurses have that reputation of being trustworthy so that definitely helps. But I think each nurse has to really strive for that trust relationship. If we want to reach that patient, where they are and help them to understand their disease process or why it's important to eliminate certain food items or change behaviors and such. And that's all on that foundation of the nurse-patient trust relationship.

Tabitha articulated a common sentiment that nurses are afforded a high level of trust as part of their healthcare role when she stated, **"**I think right from the get-go, we are trusted. I really do believe that. Even in hospitals, doctors, they'll save your life, but who's going to *keep* you alive? It's the nurse who can keep you alive." However, she went on to clarify her beliefs when she stated, "I think we start out on top and if we screw up, that's when we're going to kind of fall down on the scale." She continued further by explaining how this implicit trust contrasted with what patients would grant physicians, whom she felt were perceived by patients as less altruistically oriented. She speculated, "We're [trusted] over doctors, we're often on par with pharmacists. It's a shame because patients have come to maybe not trust their doctors because there's kind of this perception that they're greedy, and ordering tests and things you don't need."

Interestingly, a telephonic approach for patient engagement did not seem to be a limiting factor in educators' perception of automatically receiving trust. Olivia, a telephonic educator for patients with a terminal neurodegenerative condition, believed imbued trust was an innate part of her role. However, she also pointed out that patients' perceptions of honesty and transparency were also important. She described it this way, "I think people innately trust and respect us overall. But I think when you're honest, genuine and transparent with people, it goes a long way. Even telephonically, you can get that across to people. They know when you're being honest." Lois, another telephonic educator for a drug that treats chronic autoimmune conditions, shared how leveraging implicit trust was an important asset for helping her patients gain confidence in her abilities even though they were only connecting over the phone. She noted, "If they don't believe you know what you're talking about, they may not listen or learn. So, even

if it's saying, 'Yes, I'm a nurse. I work with this particular drug' …Anything to give them confidence in me is important."

Not all educators were convinced though that trust was something automatically afforded them simply because of their role. When asked a question about this phenomenon, Evelyn, an educator for a terminal neurodegenerative disease, stated, "No, I think you have to earn it. Well, I'd say maybe it could be implicit, but you really do have to earn it." Ursula, a diabetes and osteoporosis product educator, held similar beliefs. She explained how the "white coat" that may have promoted implicit trust in other geographies, would not work with her rural Southwest patients. She put it this way, "I don't think because you've got a white coat on…I'm not sure people relate to that, at least my rural people. Just because you're a healthcare professional, I don't think that comes with trust necessarily. You have to earn it."

Establishing trust. When educators spoke of earning patient trust, many of them discussed the importance of establishing it quickly at the start of their relationship with patients. Janelle, who trained patients with many different types of rare conditions, framed it in the context of letting patients know from the get-go that she would always be there for them. She stated, "Yeah, I mean, you have to go in and try to sell that, but I had to display confidence and to instill that trust in them that yes, I will be available; yes, I will have your best interest at heart." Evelyn, an educator for patients with a terminal neurodegenerative condition, believed that a good way to instill patient trust was to immediately try to understand each patient's personal disease journey. She explained, "I always start with the beginning because I think it's important to know, how did you get where you are today. What led up to your diagnosis? And I think they just start talking

and establish that sort of trust." Reba, a diabetes educator, shared that her goal was to develop a sense of trust with patients before even beginning to deliver her program content. She believed she could accomplish this by being outgoing, welcoming, and reinforcing her willingness to address any questions or concerns patients may have about their disease or therapy. She put it this way, "I tried to establish trust before I started the dialogue or program…I always tried to be real outgoing, welcoming, and letting people know there wasn't any question too insignificant...It was sort of like setting up rapport before the program started."

Penny, another educator for patients with a terminal neurodegenerative condition, felt she was often able to immediately initiate a trust bond with patients by sharing personal anecdotes regarding her life and why she became a clinical educator. She shared, "I explain to them why clinical education is important and why I became a clinical educator based on my personal experience as a caregiver…They want to know you're a person who cares, not just somebody from the [pharmaceutical] industry." Deandra, an educator of products for patients with rare diseases, however, summarized the overall importance of immediately establishing trust for succeeding with patients. She said, "It all happens with that first visit. It's either sink or swim. You're going to either make that treatment successful or you're going to kill it by the way you present it to the patient and that trust is huge."

Maintaining trust. Most of the clinical educators engaged with patients through multiple interventions over an extended time period. Therefore, they recognized that while initiating trust at the start of the relationship was imperative, it had to be continuously maintained throughout their tenure with patients. Antonia was an educator

for patients with a terminal neurodegenerative condition with whom she would meet monthly over the course of the year. She felt that one of the primary reasons her patients found it difficult to establish trust relationships with healthcare providers (HCPs) was because they did not take the necessary time to try to establish one. Therefore, she strove to make sure patients understood that she would provide them the time they were seeking. She stated, "I tell my patients, 'I'm here until we both are comfortable that you understand.' So, having that kind of trust. 'I'm not leaving, I'm not in a hurry, I'm here until we're both comfortable with what you need.'" Nadine, a telephonic educator for a program that included multiple engagements with patients with chronic autoimmune diseases, shared similar views that her role as a nurse, both in the field and as an educator, afforded her more time with patients. That extra time therefore correlated to a stronger trust relationship with patients than they may have experienced with their physicians. She explained, "Some patients feel that nurses have more time to spend and can invest more and listen than the doctor…A lot of times the patients will ask questions they don't feel they can ask the doctor for those reasons."

Antonia also recognized her time with patients did not mean that she was responsible for dominating the conversations. Patients needed the ability, opportunity, and encouragement to share their journey and its struggles, lest they not fully engage in the relationship. She said, "To be effective, [patients] need to develop trust in you and that takes time…It has to be about them. You really have to say, 'Tell me about yourself, tell me about your journey. What are your struggles?' That takes time."

By far though, "open and honest" interpersonal communication was a frequently noted strategy that educators stressed was necessary for earning and later maintaining

trust. In fact, multiple educators used that phrase to describe its relationship to trust. Ursula, a diabetes educator, posited, "I think just talking to people and being open and honest and caring, then hopefully you've got that trust." Olivia, an educator for a terminal neurodegenerative condition similarly noted, "But I think that when you're just open and honest and genuine and transparent with people, that it goes a really long way." Others, such as Sophie, a diabetes educator, framed this notion in the context of a partnership with the patient based on two-way dialogue and decision making. She shared, "I will find out, 'What are your barriers, your fears?' And go from there…If they had experience with insulin, what dose did they remember being problematic? Just gives them a say in it…and then you build that trust that way." Other educators supported Sophie's belief that conversations needed to include active listening on the educators' behalf to nurture and sustain trust. Nadine, a telephonic educator for patients with chronic autoimmune diseases, explained the importance of non-judgmental and engaged listening for helping build a sense of connectedness between herself and the patient. She shared, "Part of gaining trust is asking them about themselves, being nonjudgmental, letting them speak, not speaking over them, being a good listener...paraphrasing what they said…it helps them to trust, 'This person is listening, they do understand, they do get me.'" Karl, a colleague of Nadine's, articulated a similar vision of the role of active listening, as well as two other component that he felt were an important part of the formula for maintaining trust, honesty and keeping his word. As he explained it, "I'm always being honest…I keep my promises. If I tell my patient I'm going to be at their home at 2:30 PM, I will be there…The other thing is active listening…those are the things paramount to developing trust with somebody." Zara believed that the rapidly

evolving nature of chronic diseases like diabetes, along with the complexity of their therapies, required her to continuously educate and solicited questions from patients in order to maintain their trust. As she described, "I explain why their doctor prescribed them, what makes them diabetic, what does diabetes mean. I'll go over their labs and help them to understand…Just taking the time to answer questions...I think that's what helps people to have trust."

While the highly regulated nature of the clinical educator role did present communication challenges, many educators believed that a strong trust bond with patients mitigated the impact of compliance factors. For instance, Deandra, an educator for autoimmune and rare diseases, spoke of how trust was maintained when she was required to share a product's risk profile as part of her obligation to fair/balance presentation. She explained, "I think that's important if you're to develop trust and credibility. If they think you're pulling the wool over their eyes or trying to sugarcoat something, they're going to shut you off and their mind is going to go elsewhere." Additionally, Evelyn, an educator for patients with a terminal neurodegenerative disease, noted that trust was maintained when she disclosed to patients the limitations she faced regarding on-label compliance and her need to sometimes defer patients' questions to their healthcare provider. She stated, "I think I actually get more trust when they understand that you're doing whatever you can within the parameters of how you can do it to do what you're going to do." A similar sentiment was expressed by Bonnie, a telephonic educator for numerous chronic conditions. In fact, she believed that expressing her frustration with on-label compliance limitations to patients facilitated a sense of a "shared experience" that reinforced her bond with them. She put it this way, "I think [my inability to speak off-label] validates

the trust because they know I care, they know that I'm a little frustrated or unhappy…because we're sharing that experience together…that strengthens the bonds and rapport more so than it harms."

Janelle, a telephonic educator for patients with rare conditions, even went as far as to offer to reach out to patients' HCPs directly regarding off-label questions. She shared how this served as a gesture of trust for those patients who were uneasy asking questions to their HCP. She explained it this way, "I say, 'You're welcome if you want to go into your next appointment and say, "You should call the nurse advocate on the phone." I'm happy to chat with them, explain anything they would want.' I feel like it's an extra added benefit."

Losing trust. Though educators understood the benefits and necessity of a strong trust bond with patients, they also recognized the impact when trust was lost or never acquired. Bonnie, an educator for many different disease types put it succinctly, "There's just no way that you could get somebody to recognize what's in their way and how they can take the first steps to try to change that or overcome that if you don't have that trust." She went on to elaborate that, in her role as a telephonic educator, a loss of trust will curtail patient communication and impede the progress toward overcoming barriers. She stated, "If you don't have trust, there's not any way to help people when they have barriers, concerns, or they're upset…I mean, why would you tell people your challenges about your health and life, especially if you don't know that person."

Penny, an educator for patients with neurodegenerative and neurological conditions, noted that trust losses run the risk of impacting patients' ability to absorb knowledge and develop the skills necessary to self-manage their condition. She

lamented, “You can educate on materials, but if they don’t trust you, do you think it’s going to resonate in their lives? Are they going to absorb what you’re teaching and really practice and benefit from it if there’s no trust?” Janelle, an educator for patients with rare diseases, associated a patient’s lack of trust in her to also mean a loss of credibility. She believed this could put the patient at risk for not properly managing their disease or causing them to revert to negative emotions. She explained,

> If I don’t seem credible and I don’t seem like I know what I’m talking about, they’re going to lose all trust and resort back to a feeling of worry, despair, potentially hopelessness. If I don’t sound competent, if I don’t appear confident, if I don’t seem like...to know what I’m talking about. So, I feel like trust is a huge thing for them to be able to transfer that trust into confidence in themselves, to take on that understanding of things.

The clinical educators were keenly aware of the actions or situations that would put trust at risk. For instance, Olivia noted the potential damage to trust that could arise if educators ignore expectations of proper follow-through and time management. She explained how these factors were particularly important for her population of patients who suffered from a terminal neurodegenerative condition and were physically and emotionally reliant on her. She described it this way, “I think you can lose [trust] and can disappoint people if you don’t follow up, if you don’t follow through…you’re not going to feel a lot of love for me. Especially in this disease [where] the only outcome is death.” Deandra, a telephonic educator for rare diseases, explained that an educator’s lack of preparedness or familiarity with the therapy on which they are educating can also extinguish a trust bond. She reflected, “When a nurse goes into a home and…says to the

patient, ‘Well, I’ve never done this before but we’ll figure this out. We’ll get this done.’ That patient’s trust and confidence in this nurse has just been shot to hell.” Nadine, an educator for patients with chronic autoimmune diseases, felt that privacy losses could negatively impact the trust relationship, even when the loss occurs within the patient’s family. She explained it this way, “If the patient told you something and wanted to keep it private. But when the spouse walks in, you blurt it out, you just shot any chance of that patient confiding in you. That shoots trust right out the window.” Nadine’s beliefs illustrate the concept of loss of trust credit points (Petronio, 2002), which are figurative points that can increase or decrease based on educators’ privacy actions, and underscores the intertwined nature of the constructs of trust and privacy. The next theme explores this relationship between trust and privacy and examines how educators manage disclosed information from patients through privacy rule decision criteria.

Disclosure Rules and Privacy Management

Theme 6: Educators managed the information disclosed to them by patients using routinized rules based on core privacy rule decision criteria as well as changing rules based on catalyst privacy rule decision criteria.

Educators recognized that patients’ willingness to disclose private health information was predicated on a strong trust-based relationship. They also understood that the nature of their role as an HCP predisposed them to a level of trust that, for the most part, allowed for such disclosures to happen with little resistance or skepticism. Not surprisingly, when educators were asked during their interviews to reflect on the meaning of the concept of privacy in the pharmaceutical clinical educator role, they rarely spoke about it in the context of communicating information about themselves to patients or

others. Instead, one of the ways educators addressed the topic was by explaining their perceptions for how patients disclosed disease and therapy information to family, friends, and others—views educators accumulated from their conversations and observations with patients. They noted that patients' behaviors varied, with some being open toward talking about their condition while others kept that information guarded and protected. Those descriptions highlighted educators' interpretations of how patients established varying levels of boundary permeability (Petronio, 2002). Educators also provided examples of the way influencing factors impacted the decisions patients would make about information disclosures. These examples were illustrative of CPM's two categories of privacy rule decision criteria, core criteria and catalyst criteria. The former describes criteria that is stable and works in the background, while the latter explains criteria that fluctuates based on situational triggers (Petronio, 2002; 2013).

The other way educators addressed the concept of privacy was by describing disclosure expectations placed upon them by different groups including patients, government, and themselves. Educators recognized that, as recipients of patients' private information, patients had expectations regarding how educators managed that information. Additionally, educators also placed expectations upon themselves about when, where, why, how, and to whom patients' information was shared. However, while educators were co-owners of patients' private information, they engaged in little boundary coordination with those patients. In CPM theory, boundary coordination is when the information owner (i.e. the patient) and the recipient of that information (i.e. the educator) coordinate decision rules regarding disclosure boundaries (Petronio, 2002). Those rules determine such things as how private information is used or shared as well as

to whom and when it can be shared. While little privacy coordination occurred, educators still used and followed a set of routinized rules based on core privacy rule decision criteria as well as adapted to changing rules using catalyst privacy rule decision criteria.

This theme examines clinical educators' understanding of the concepts of trust and disclosure within their definition of privacy. This examination begins with an explanation of how the trust relationships established between patients and educators were foundational to educators' and patients' privacy management behaviors. Next, educators' descriptions of how patients' managed privacy disclosures with their family, friends, and others are provided. Included with those descriptions are interpretations of why those patient stories are representative of the CPM constructs of boundary permeability and core and catalyst privacy decision criteria. The insights educators gleaned from patients' disclosure behaviors served to influence educators' own beliefs about privacy management and the clinical educator role. Lastly, the routinized and changing privacy rules educators used, along with their respective core and catalyst decision criteria, are discussed within the context of three influential parameters—professional ethics, political/legal ecological factors, and insights from patients' privacy management behaviors.

Trust and privacy management. Trust serves as a foundation for managing privacy disclosures across all forms of interpersonal engagements. The educator-patient relationship is no exception given the nature of information that is disclosed by the patient to the educator and the role the educator serves in patients' disease self-management. In Petronio and Sargent's (2011) explanation of the stakeholder confidant

role, a concept discussed later in this chapter, the authors outline why healthcare professionals tend to be afforded trust easily by patients. They note that patients give guardianship of their information to HCPs because it is predicated on both the functional need to receive healthcare as well as a perceived level of trust. Such an assertion is supportive of educators' previously noted belief that their clinical credentials predisposed them to a level of trust not provided to other professions. As noted earlier, Petronio (2002) refers to this predisposition of trust as "trust credit points." For instance, violations of patients' disclosure rules can lower the number of credits which, in turn, may decrease the amount of boundary permeability in the educator-patient relationship.

Educators fully believed that patients' expectations of privacy were directly associated with the nature of the trust relationship that was established between them. As Penny, an educator for patients with a terminal neurodegenerative condition, stated, "I think they go hand in hand. It's one of the components of trust, privacy." Many educators felt that patients' willingness to disclose private information was predicated on a strong trust bond established at the start of their engagements. Karl, a diabetes educators, held such beliefs when he stated, " If you were able to develop the trust at the beginning, then [patients] might be more willing to give you that information versus if you didn't develop the trust then it's probably likely they won't give it to you." Nadine, an educator for patients with chronic autoimmune conditions, supported this contention when discussing her telephonic patients, whom she spoke with over the course of multiple weeks. She stated, "But then after they warm up to you, and you're on to your next call. You do form a relationship, and they start to trust you and open up to you." Hanna, a diabetes and osteoporosis educator, reflected on her earlier experiences of working in the field and

charting patient disclosures as part of their medical history. She explained the importance to the trust relationship of reassuring a patient that all disclosures are held in confidence, regardless if they are relevant to the patient's clinical need. She stated,

> The patient needs to know relevant things to their visit may find their way into a note chart. But if something is disclosed has no bearing on that, they need to feel confident that, should they tell you something in confidence, it would be held that way.

Later in her conversation, Nadine explained that part of her role as a trusted confidant is also being able to read the verbal and nonverbal cues that indicate why a patient may cease disclosure. She described what she might do to maintain trust if it were clear that a patient's disclosures were jeopardized by the presence of a family member with whom the patient was not comfortable having in the room. She stated, "Maybe that patient doesn't want their husband to hear what they're saying—you take those verbal and nonverbal cues from the patient…I'd change the subject, so privacy was kept. That plays a big role in trust, it all goes together." Penny articulated similar beliefs about the relationship between trust and privacy as it pertained to navigating disclosures within a patient's family dynamics. In her example though, a patient's wife was disclosing information about her husband that she wanted Penny to hold in confidence. Penny believed she was equally obliged to honor the confidentiality of the caregiver's request in order to preserve the trusting relationship among all three parties. She shared, "I was talking to a caregiver and she said, 'I wanted to talk because my husband's really overwhelmed.' So, my relationship with that caregiver is different than my relationship with the patient. But then trust is important, privacy is important." Earlier in her

interview, Penny had also expressed that it was important for educators to view these constructs beyond their context in government-related privacy protection mandates such as the Health Insurance Portability and Accountability Act (HIPAA). She used the metaphor of "building a bridge" to express how assurances of privacy strengthens trust. She reflected, "It's important because it's part of HIPAA. Also, if I tell them that everything we talk about remains confidential, between you and I, and of course, with your physician too…just by saying that helps build that bridge towards trust."

Educators strove to protect the privacy of the information disclosed to them by patients because doing so was foundational to maintaining trust. Additionally, educators recognized that such confidentiality was not only an expectation the patient had for them; it was also an expectation that patients had toward others. The next section examines educators' interpretations of the beliefs and privacy rules that guided their patients' personal and public disease disclosures.

Educators' interpretations of patients' privacy management. Throughout their interviews, educators offered stories and assessments of how patients managed their disease information with others. Such actions would later influence educators' own beliefs about privacy management. The examples are indicative of multiple constructs within the CPM theory framework. For instance, one such interpreted concept was boundary permeability, the notion that an individual establishes disclosure boundaries in figurative degrees of thickness (Petronio, 2002). Educators also described situations and experiences that were illustrative of patients' use of privacy rule decision criteria to manage the way they shared health information with family, friends, and others. Some patient examples were representative of core decision criteria, such as cultural

expectations and personality characteristics, which are defined as stable criteria that tend to operate in the background. Others aligned to CPM's constructs of catalyst decision criteria, which are circumstance-based criteria that can trigger a change to pre-established privacy rules. Examples of these criteria, interpreted from educators' descriptions, include motivational goals and risk-benefit goals (Petronio, 2002; 2016) .

Educators recognized that each patient was unique in the way they would allocate varying degrees of access to others regarding information about their condition and therapies. Such descriptions were akin to CPM's concept of boundary permeability in which thin boundaries represented a high level of comfort toward sharing private information to others, whereas thick boundaries represented a high desire to protect that information (Petronio, 2016; Petronio, 2002). Reba, a diabetes educator, described such a phenomenon when she shared,

> There are some people who, with diabetes for instance, they don't want anyone to know they have it, and they want to keep it very personal, private, and confidential. Sometimes even to hide it from immediate family members. Then there are other patients who, they don't care if the whole world knows that they have a chronic health condition like diabetes. For some…it's just, 'This is me, and this is the way I deal with life.' So, I usually saw both extremes.

Cora, an educator for numerous chronic conditions, maintained a similar understanding, even going as far to express that confidentiality protection—however that was defined by the individual—was a patient right. She stated, "Confidentiality is a big thing because that's a patient right. They have their information protected, and not everyone wants

everyone to know they have diabetes. Some are open with it and it's part of their life, others don't want that."

Educators respected and felt obligated to protect the level of boundary permeability each patient established for their personal and public disclosures. However, educators still had their own beliefs and opinions regarding the benefits and drawbacks of how patients managed privacy. For instance, Reba noted that there was a risk to her diabetes patients who established thick disclosure boundaries with coworkers, particularly if a patient experienced side effects related to their medication. She explained that a hypoglycemic event could be misconstrued as poor mental health or drunkenness and thereby damage the patient's reputation. She shared, "Hypoglycemia can be a serious thing if it happens in the workplace. If you wanna keep your diabetes very private, then coworkers may think the worst…thinking they're drunk if they have a serious low blood sugar, or they're psychologically unfit." She went on to express her belief that patients' with low tolerances for public disclosures related to their disease are at risk of unintended consequences. She said, "So, it definitely makes a difference in how the person with diabetes relates to the rest of their environment, depending on whether they want their diabetes to be public or private." Reba's statement demonstrates an interpretation of the potential outcome that could arise from a patient's insufficient risk-benefit ratio calculation, one of CPMs catalyst decision criteria (Petronio, 2002; 2016).

Educators also understood the importance of never making assumptions about the types of privacy boundaries patients may have established with others, particularly as it related to a patient's family. As Iris, an educator for chronic autoimmune diseases, noted,

"Believe it or not, a lot of people don't tell their spouses or their families or their kids what's going on with them. They consider that that is their private information." Whitney, another diabetes educator, shared an example of privacy protections taken to an extreme. She described the excessive measures one of her patients took to keep anyone, including his spouse, from knowing he had diabetes. She shared, "I've one guy that brings his meter in a bag because he doesn't want anybody to know. His wife doesn't know he's diabetic. It's 'close the door' when you're talking to him. I can't say out loud he has diabetes." Like her peers, Whitney respected that patient's right to manage his disease disclosure in a way in which he was comfortable. Her description of her patient's disclosure behavior demonstrate the influence of an individual's personality characteristics, one of CPM's core criteria of privacy rule decision making (Petronio, 2016; Petronio, 2002). In fact, that patient's extreme measures of privacy protection would support Petronio's (2002) contention that individuals with high-Machiavellian personality characteristics (i.e. holding cynical views of human nature and internalized manipulative personality traits) are low disclosers of information.

Vivian, a diabetes educator, discussed a belief that patients' disclosure tolerability can be culturally influenced. Such an understanding is illustrative of CPM's cultural expectations, another of the core criteria for privacy rule decision making (Petronio, 2002; Petronio, 2016). She explained how, in her own personal experiences, she had knowledge of the general medical histories of her immediate and extended family. However, she was surprised when documenting family medical histories for some of her African American patients with diabetes, to frequently hear the response "I don't know. We never talk about that kind of stuff." From those interactions, she came to believe that

a patient's cultural experiences influence the disclosure dynamics within a family. She shared, "It's a whole new concept for me. I just didn't understand, but then I find out that in the African American population that, clearly that's not something they share. Sometimes, even the husband doesn't know what illnesses the wife has." Studies in the literature would support her view that African-Americans are less likely to know their family medical history (Lin et al., 2018; Murff et al., 2005). Vivian went on to explain how that newfound knowledge helped her adjust her approach when engaging patients in private conversations, particularly if others were in the room. She said, "I always ask, 'I'm with the diabetes team, is now a good time, or you want me to come back a little bit later?' Especially when there's people in the room, even if it's family."

Not all educators though spoke of thick boundaries and guarded disclosures. Tabitha, a diabetes educator, provided an example of how motivational goals, one of CPM's catalyst criteria for privacy rule decision making, can change patients' boundary permeability (Petronio, 2016; Petronio, 2002). She reflected on her experience of soliciting patients whom she helped overcome disease obstacles, to become advocates for others she taught. She explained, "Once they mastered it, they were pretty proud of themselves and willing to share if I asked them, 'Would you be willing to come and speak at one of my classes?' Nobody ever said no." Tabitha hypothesized those patients' willingness to be forthcoming about their diabetes was motivated by inherent altruistic tendencies possessed by all people along with a sense of comradery that emerges from helping others successfully navigate the shared experience of a disease. She posited, "Once people are comfortable with something, and they think they can help because,

we're basically kind, good people, I believe that. When you feel you can offer something because of the experience you've gone through, you're willing to do that."

The insights educators gathered from witnessing how patients navigated disclosures with others, influenced the educators' own beliefs about privacy management in their role. The next section examines the application of those beliefs in the communication actions educators would take with patients.

Educators' privacy management of patient information. Educators managed their patients' private information in the same way their patients did, using rule decision criteria. Like their patients' rules, the decision criteria were grouped into two types, core criteria and catalyst criteria. As CPM theory explains, most core criteria are representative of routinized properties. Routinized rules develop when an individual adopts rule criteria that become stable and promote "routine" privacy behaviors over long-term use. Conversely, changing rules, as the name implies, are rules that are apt to change because of a triggered catalyst rule criterion (Petronio, 2002; 2016). For the purposes of this study, routinized and changing rule properties were identified within three types of parameters—privacy rules that arose from educators' professional ethics, rules that were generated by educators' adherence to political/legal context factors, and rules that were created based on the insights educators' gathered from the way their patients' managed privacy. For the most part, the rules that were influenced by an educators professional ethics or political/legal context factors tended to be routinized; both parameters were stable and were abided to prior to their role as a pharmaceutical-sponsored educator.

Professional ethics and regulations. Many of the rules the pharmaceutical-sponsored clinical educators established for managing their patients' disclosures were adopted from the privacy expectations that guided them when they worked in the field. Gabi, an educator for chronic autoimmune conditions, explained such behavior when discussing the sharing of patient information with others. She summarized it this way, "I wouldn't share with anyone about the patient or their home. Just like you would for a patient in the hospital or clinic, you wouldn't share that information with anyone else." Gabi equated the privacy rules she followed in her pharmaceutical educator role to be the same as the ones she would adhere to in her previous clinical roles. Such equivalences were a common interpretation of proper patient privacy management among many educators, including Cora, also an autoimmune disease educator. Cora stated, "When you're one-on-one, all that information is kept confidential, and you respect the patient just as you do in any other aspect of healthcare. That's private information, and if they want to share that information, it's up to them."

Cora's use of the phrases "you respect the patient" and "if they want to share that information, it's up to them" highlights that it is her deference to patient autonomy that drives the privacy rules she maintains about disclosure. For Cora and Gabi, proper management of disclosed information is a professional obligation, rooted in the ethics that orient them as healthcare providers. Later in her interview, Cora reinforced this notion when she stated, "I guess in healthcare, we try to encourage people, but yet we have to be very careful because...It's ultimately up to them, and we have to protect their wishes and protect their privacy and respect that." Iris, an educator for multiple chronic conditions, held a similar attitude and referenced how respecting privacy extended to the

conversations about patients she had with her professional colleagues. She maintained, "You definitely don't want to reveal to anyone, even speaking with my other nurse friends, I never reveal names if I'm telling stories …but privacy, you truly have to respect what information patients want to keep to themselves."

While educators' professional ethics served as a compass that provided direction for how, when, and to whom to disclose information, those same ethics could also push them to breach privacy if a patient's safety was at risk. For instance, as noted in Chapter 4, both Iris and Antonia shared dilemmas they faced when a patient and a caregiver disclosed suicidal intent. Both noted that, in those instances, their professional and legal responsibility as a healthcare provider is to get immediate help for that individual regardless of privacy expectations. As Antonia acknowledged about her suicidal caregiver situation, "But some things we are, as healthcare professionals, required to divulge." Janelle, an educator for patients with rare diseases, also admitted that this was the exception to the disclosure rules created to protect patient autonomy. She stated, "If they say something that'd give me pause, I'd be 'Well, this is why we shouldn't do that'...The thing is, if any HCP hears something that could be harmful, we've a duty to advise them to speak with the doctor." These examples demonstrate how a situational condition (i.e. suicidal ideation) could serve as a catalyst criterion that would trigger changes to educators' ethically based routinized rules regarding disclosure.

Political/legal factors. As noted in Chapter 4, political/legal ecological factors, manifested in government and industry-imposed compliance regulations, influenced the communication dynamics between educators and patients. Not surprisingly, some of these factors evolved into routinized rules that guided educators' management of patient

disclosures. However, unlike professional ethics rule decisions that arose from educators' internalized beliefs about respect for patient autonomy, political/legal rule decisions originated from external forces. These forces included federal policies such as HIPAA, pharmaceutical anti-kickback legislation such as the Sunshine Act, and government guardrails that dictated the type of contact between pharmaceutical industry representatives and patients. Together, these factors encouraged educators to create and abide to privacy management rules that carried the weight of the law behind them. Karl, a diabetes educator, articulated this understanding when he stated, "[Privacy] plays a huge role. We know the rules that we have to protect privacy. You want to protect personal health information. There's HIPAA, there's the Sunshine Act. There are a lot of laws to protect privacy." In fact, as Karl went on to acknowledge, in some instances, educators' necessity to strictly adhere to these rules could even be disadvantageous to a patient's disclosure wishes. He put it this way, "It can be to the advantage or disadvantage to the patient. For example, the patient is supposed to get a special medication and they want you to call the pharmacy for them. You can't call because it's a privacy issue."

As Karl pointed out, political/legal factors limited who could legally receive patient-disclosed information from educators. While certain brand networks allowed pharmaceutical sales representatives to consult with doctor offices regarding patient enrollment in clinical educator programs, educators were forbidden from disclosing any patient information back to the sales representative. As Felicia, an osteoporosis educator noted, "I'm HIPAA Compliant. I can discuss patients with the physician and nurses. I cannot share names or personal information with the rep. If there's any issues, I've got to

be the one that's communicating that with the office." Martin, a diabetes educator, explained though that political/legal-based disclosure rules were not unique to the pharmaceutical educator role. Many of them are the same privacy guidelines he is required to follow as a clinician working in a hospital or physician's office. He shared an example from his experience when working as a pediatric educator and receiving disclosure requests from teachers. He said, "Something we deal with was a teacher calling to learn how to care for a child. With HIPPA, you wouldn't discuss that. It'd be 'Let's get the parents, and you come in with [them].' Privacy changed how we deliver education."

Martin's statement of "Privacy changed how we deliver education" was indicative of how political/legal factors, such as HIPAA, influenced patient privacy management across the entire healthcare industry. Martin and the other educators all had years of experience working within government and health industry-imposed privacy regulations during their prior tenure as field-based clinicians and educators. Hence, these type of privacy rules were routinized by educators and understood to be applied uniformly across all patients.

Though many of the political/legal factors that influenced educators' privacy disclosures with patients were carry-overs from their prior work in the field, some influences were unique to the pharmaceutical clinical educator role. Gabi, an educator for osteoporosis and chronic autoimmune conditions, noted that some patients had concerns about whether their health information was shared with the pharmaceutical companies she represented. She handled this situation by explaining to patients that she worked independent of the medication's manufacturer. She said, "I also usually

emphasize that I don't work for the pharmaceutical company, that I'm a third party, so that they don't think the pharmaceutical company has their information. I do bring that up." Lois, a telephonic educator for chronic autoimmune conditions, highlighted that same concern. She reassured patients that, legally, she was not allowed to provide her sponsoring companies with patients' health information. She stated, "But also, from the pharma end of it, if they ask, 'Will this information be shared?', then I have to reassure them what the guidelines and regulations are that I work with, so they understand that it's a privacy matter."

Interestingly, some educators had qualifying—even self-contradictory—beliefs about patients' perceptions of privacy rules and regulations. For instance, Lois continued by describing how part of her role's privacy management responsibilities was fielding inquiries and educating patients about the policies that were in place regarding pharmaceutical-related privacy matters. This was something she did not experience in her prior position working in a physician's office. She explained, "[Patients] wanna know if it's going to get on the Internet and they're gonna start getting marketing calls, those things. How I knew who they were, how did I learn about them? I didn't have that at the office practice." However, Lois later offered insights that qualified, while patients do have some privacy concerns, they worry about them less than what the industry perceives them to be. She stated, "I honestly think we are forced to make privacy a huge thing. But I often times feel like it's not as big of a deal to the patient as it's made out to be by all the rules and regulations."

Bonnie, an educator for diabetes and chronic autoimmune conditions, noted some similar contradictory concerns from her patients when she stated, "People want to know

who we are if it's a phone call, who are you calling with, who are you representing? They want to clarify who they're talking to." However, Bonnie latter clarified that in general, patients seemed less concern with privacy matters then the industry's perception. She posited, "People don't seem to be concerned with 'What are you doing with my information? Where does that go?' That's something we have the responsibility to manage and protect. But I don't feel it's part of their awareness and everyday consciousness."

Insights created from patients' privacy experiences. As noted previously, one thing educators learned during their prior clinical field experiences was that patients had varying views regarding privacy, particularly as it related to family. That insight did not change for their pharmaceutical educator role and therefore necessitated the use of routinized privacy rules when dealing with familial situations. For instance, Antonia, an educator for patients with a terminal neurodegenerative condition, reiterated the earlier notion, learned from the field, that educators should never make assumptions about patients' expectations regarding the disclosure of information to family members. She shared, "I don't think we should assume a patient wants family members in, I'd like to include them, but when you're educating a patient, you have to make sure they do want their family members present, because they may not." Gabi, an educator for patients with chronic autoimmune diseases shared the use of a similar privacy rule for her telephonic patients. She stated, "I'm really careful if a husband or wife answers the phone not to say what the medication's for. Because I don't know if they've discussed that with their partner."

Telephonic programs did present other privacy issues around which educators needed to navigate. Bonnie, a telephonic educator for multiple disease types, discussed how the ubiquity of cell phones often presented privacy challenges when contacting patients. She explained, "Most people have a cell phone, they could be at the grocery store, they could be at work or in a noisy environment or they could be very distracted. I do think that privacy can impact the conversation." Nadine, a telephonic educator for chronic autoimmune disease, pointed out the difficulty of securing patients' trust on the first outbound call she makes to them. She highlighted the privacy impact of patients' skepticism toward speaking with someone from an unrecognizable phone number who is asking personal questions. She reflected, "At first, they think that you're a scammer trying to get their information…during the first call you're asking a lot of questions about their date of birth, address, their family members' names. So, they're reluctant to answer anything for you." She explained that she was able to overcome the skepticism through trust messaging and reassurances of her healthcare credentials and program intent. As she explained though, this would often take multiple calls to accomplish. She said, "It usually isn't until the second call that they feel comfortable enough to talk…But after they warm up to you and you're on to your next call, you form a relationship, and they start to trust you and open up."

Educators who delivered group-based programs had unique privacy issues with which they needed to contend. Multiple educators who delivered product or disease programs using this format spoke of its challenges. Some also shared the routinized privacy rules they used to address those issues. Vivian, a diabetes educator who served rural communities, spoke of the drawbacks of group programs for patients in tight-knit

small communities where lack of anonymity could be problematic. She explained, "Some people were hesitant, didn't want to share…Sometimes it was in small towns, so people know each other. They didn't want to know that the neighbor did or didn't do something correctly. It was a little awkward at some places." Ursula, a diabetes educator, noted similar concerns while highlighting how a one-on-one setting was more opportune for personal disclosures. She stated, "I think people need to feel like they can tell you things, and probably in a one-to-one setting more things are going to come out than in a group setting, but still you have to protect people's privacy." Cora, who had experience delivering programs via interactive webinars, felt that approach was more conducive to patients' disclosure than group programs simply due to the one-way visual nature of the technology. She explained, "When we did the webinars, people were most candid and open because they could see us but we couldn't see them. Whereas when you sat in the classroom or one-on-one, those types of personal questions really didn't come into play."

Reba had spent part of her career working for a network in which patients could attend multiple group diabetes programs as part of a series focusing on different disease-related topics. She found that, in those instances, most patients tended to become comfortable with sharing personal information the further along they went in the series. However, she also clarified that this was not the case for all patients. She described, "I've had patients that it's taken weeks, a number of visits, to establish a rapport that they would feel comfortable telling me personal circumstances that impact their diabetes management. There are some patients that you may never get." While Reba shared her beliefs that patients' discomfort with sharing was not uncommon, she also pointed out

there were those individuals who were at the other end of the continuum. She explained, "Then I've had patients who really try to domineer the situation and you have to cut them back and say, 'Let's move on and give other people an opportunity to interact.' So, you usually have both extremes in a group."

Whitney, a diabetes educator, reinforced her peers' beliefs that the dynamics of the group classes can make disclosure intimidating for some patients. However, she also believed that non-disclosing patients still benefited from group programs because many would feel empowered to speak with her after the program. She stated, "I really think they get more out of group classes, because they feed off that [information]. There's sometimes in classes, people will ask you things after the fact that they didn't want to bring up with the group."

Educators understood they walked a fine line when it came to expectations of receiving personal disclosures from patients in group settings. They believed there was a therapeutic value of having patients actively participating in discussions about the shared experience of their disease. However, they also felt obligated to respect the desired privacy of patients who were not comfortable with disclosing. One way Deandra, an educator for rare diseases, handled this dilemma was by soliciting input through a gentle invitation for stories. She explained, "You invite people to share their stories, to share treatments they're on. But you don't force it. You put a general question out there. 'Would anybody like to share what treatment they're on or what it was like getting diagnosed?'" Reba offered a similar invitation to participants during her group sessions while also impressing upon the group the mandate to keep any disclosed information confidential. She explained it this way, "We said… 'Anything we talked about was

confidential, it didn't leave the room.' …I tried to introduce early on the importance of privacy. And, that patients can learn from each other, so anyone who has a question should feel free."

Educators' privacy management behaviors were managed using routinized rules based on core privacy rule decision criteria as well as changing rules based on catalyst privacy rule decision criteria. However, these rules were also influenced by the type of confidant relationship patients created with educators. The next theme addresses three of these confidant role types and examines how educators' co-construction of those roles impacted disclosure dynamics.

Clinical Educators as Confidants

Theme 7: Educators managed multiple types of confidant roles with patients including stakeholder, deliberate, and reluctant.

CPM theory asserts that recipients of disclosed information co-create various types of confidant roles with the discloser to include deliberate, inferential, reluctant, and stakeholder (Petronio, 2002; Petronio & Sargent, 2011). These roles are flexible and situationally based as an individual's confidant status can fluctuate based on the context or content of the disclosed information. Additionally, the privacy rules that are generated between the discloser and the recipient also vary among confidant types. The deliberate confidant is an individual, such as a counselor, therapist, or coach, who receives private information because it is solicited. The inferential confidant is someone who expects to give or receive disclosure because of the nature of the relationship, such as a wife to her husband or a child to their parent. The reluctant confidant is someone who receives private information, intentionally or inadvertently, without an expectation for such. An

example of this role is a passenger on a plane to whom a stranger discloses information (Petronio, 2002). Lastly, in the domain of healthcare services, there are those who operate as stakeholder confidants. These are individuals, such as doctors, nurses, and other patient-facing health professionals who, by nature of their healthcare role, receive patients' private health information (Petronio & Sargent, 2011).

Data from this study suggested that pharmaceutical-sponsored clinical educators represented three of the four confidant roles—stakeholder, deliberate, and reluctant. This theme further defines those three confidant roles within the context of the educator-patient relationship. This includes an explanation that helps delineate the stakeholder and deliberate confidant role as they relate to the clinical educators in this study. The stakeholder confidant role is explored first, followed by the deliberate confidant role. The section ends with findings regarding the reluctant confidant role.

Clinical educators as stakeholder confidants. For the purposes of this study, an educator's role as a stakeholder confidant is examined in the context of an individual who solicits and receives patients' health information as a function of their clinical credentials and/or perception of them by patients as a de facto HCP (Petronio & Sargent, 2011). This clarification is provided to avoid confusion with the deliberate confidant role that is described later in this chapter. A stakeholder confidant is an individual who becomes a co-owner of patient's personal health information because they are a stakeholder in the patient's care (Petronio & Sargent, 2011). As such, this type of confidant is expected to manage and protect that information out of a responsibility to patients and a professional obligation to their field (Brann & Mattson, 2004). The pharmaceutical-sponsored clinical educator has a unique role though, in that they are not part of the patient's formal

healthcare team; rather the educator is tangential to the team. However, like a traditional HCP member, the clinical educators for this study were often afforded access to patients' private health information when it was disclosed to them by patients or when it was provided as health data during the enrollment process. Unlike a member of the formal healthcare team though, the historical data accessible by clinical educators was limited; rarely would an educator possess a complete medical history. Hence, this proved to be a challenge for educators who sought to deliver customized educational engagements. Still, because the educator was able to establish a therapeutic relationship based on the necessity of helping patients manage their disease, patients typically perceived educators as de facto guardians of information.

Felicia, an osteoporosis educator, noted that while patients may not completely understand her role, she still served them in a manner that was representative of stakeholder confidant characteristics. She attributed this phenomenon to the trust patients placed in her nursing credentials as well as the trust patients afforded her because she was viewed as an extension of the physician. She shared, "Not everyone understands, they know I'm a nurse, and I'm coming to teach them. And I've got their information from their doctor. So, he must trust me if he gave me their information. So, kind of opens up the communication." The concept of clinical educators as "extensions of the physician" was similarly described by Yvonne, a diabetes educator. She explained that patients sometimes viewed her this way, especially when they had complaints about other staff who worked in the office. She stated, "I've had people complain about the person at the front desk—never a problem with the doctor but complain about the person at the front desk because they know I'm an extension of the doctor." Bonnie, an educator for

numerous disease states, believed that generational views of the patient-provider relationship was a factor in why older patients often perceived her as a stakeholder confidant. She felt that that population tended to have a more paternalistic interpretation of physicians and members of their healthcare team. Hence, as an extension of the physician, she took on stakeholder confidant responsibilities. She noted "That [paternalistic approach] works for some people a lot, especially the older population. In that case, an educator might continue that role and try to just follow through."

Educators felt they were automatically imbued with stakeholder confidant status because of their credentials and their tangential relationship to physicians. However, there were two other reasons why they achieved this type of confidant status—the way they defined expectations of themselves to patients, and the ease with which they were accessible for communication. For instance, Antonia, an educator for patients with a terminal neurodegenerative condition, would explain her responsibilities to patients in a way that acknowledged her connection to a pharmaceutical company while also implying she is a de facto member of the healthcare team. She put it this way, "I let [patients] know they can call me about pretty much anything, but I explain that I work with [drug name]. Anything around my drug, you can call me about. But I end up navigating a lot of general stuff." Yvonne, similarly acknowledged to patients that her role and her responsibilities extended beyond the drug company for whom she works. She made sure patients understood that she is first and foremost a healthcare provider. She would say to them during engagements, "Keep in mind, [pharmaceutical company] signs my paycheck. With that in mind, when this job is long gone, I'll still be a diabetes educator. Our product may not be the best. I'm totally prepared to tell you that."

Janelle, an educator for patients with rare diseases, shared how she would frequently serve as a surrogate for patients' physicians simply because she was more easily accessible via the phone. However, she explained that often times the objective of the call was simply for her to serve as an outlet to which patients could vent disease frustrations. She noted, "People get upset because either their doctor isn't taking them seriously or isn't calling them back because they're really high needs. They end up calling us because we'll answer the phone, and they just need to vent." Lois, a telephonic educator for chronic autoimmune conditions had similar beliefs. She stated, "It's more convenient for them to reach us than to get someone at the doctor's office to return calls or get answers. We pick up the phone or respond to voicemail within a quick timeframe. So, they call us first." Lois went on to clarify that, given the compliance guardrails she was required to follow, she oftentimes had to refer patients back to their physicians' offices anyway to have questions and concerns fully addressed. She noted, "I'll get calls from patients asking what their dosing schedule is supposed to be. I can tell them what it is for in the FDA guidelines, but I have to refer them to their doctor's office to confirm that."

Petronio and Sargent (2011) explained that one of the reasons patients established stakeholder relationships was because of their need to disclose emotions about their medical state. In other words, patients trusted that HCPs would help manage the range of emotions that were related to the disease journey. When patients perceived they could trust the educator, disclosure came more easily. Quinn, a diabetes and osteoporosis educator, summarized this notion succinctly when she stated, "I believe it's the trust thing. I don't know why that happens. I can only speak for myself, but I have patients that

will pour their whole life out to me while I'm sitting there with them." Educators understood though that disclosures were still predicated on establishing the sort of trusting relationship that was genuine and comfortable. Otherwise, as Ursula, a diabetes educator noted, patients could present a façade of confidence that masks hidden anxiety. She explained, "You really had to gain somebody's trust to start with, so they share things with you and didn't just 'yes' you. You know? 'Yes, yes' and meanwhile in their head they're going 'No, no. there's no way I'm doing that.'" Nadine, who managed other educators, admitted that engaging patients in discussions beyond what was outlined in the script guides helped provoked disclosures because it reinforced trust. She stated, "Even the seasoned nurses will not always talk about the topics on the scripts. They'll have general conversations…But that's the part of forming that relationship and that trust with a patient and letting them talk about what's pressing to them."

Felicia found that once that trust was firmly established, deliberate disclosures from patients could even occur long after an engagement. She shared an example of a patient who contacted her months after a training session to provide an osteoporosis status update. She shared, "There has to be trust that develops over phone calls for them to welcome me into their home. I had a patient call me that I haven't seen in a year to let me know her bone density result."

Additionally, patients confided in educators in a stakeholder way because the trust bond between them created a safe and comfortable environment for sharing. In fact, many educators highlighted how their engagements frequently functioned as a type of social outlet for patients. Janelle noted this was the case for her rare disease patients who often felt isolated by having a disease to which few others could relate. She explained,

"For the rare disease that I'm currently working with, they disclose a lot. They will tell you anything and everything...I feel like they just are constantly looking for an outlet, so they will say anything and everything." Hanna described this same sort of openness toward sharing from her osteoporosis patients, many of whom were widows who simply enjoyed her company. She reflected, "Two thirds of the patients I visited have been widows. So, it's their social outlet…I love my ladies. I have a fabulous time. If I don't get 'Come back for dinner if you're in the area,' I've done something wrong." Like Hanna, Quinn also found that a subset of her older patients was lonely and therefore viewed her programs as an opportunity to engage with someone conversationally. Hence, they disclosed freely. In fact, Quinn acknowledged that some of those engagements eventually blossomed into friendships. She shared, "A lot of them are still my friends. I still talk to them. And some of them don't have anyone to talk to. You walk into the home, and you're all they've talked to in the last week or two." Quinn continued by stating that she believed such connectedness with patients reinforced the notion that her role was to be an advocate for them. She said, "But they get to where they know you're an advocate for them and when they feel like you're there for them, that makes a big difference."

Educators' ability to offer a venue for social outlet benefitted other patients in addition to those who were lonely or suffered from rare conditions. Nadine, a telephonic educator for chronic autoimmune conditions, described how she often functioned as an empathetic ear for patients frustrated with unsympathetic family members who did not understand the disease journey. She explained, "You've got somebody that's supportive, that you can talk to about barriers. Or maybe you don't want to burden your family

anymore…It's refreshing for the patient to have somebody that's not a family member and understands what they're feeling." In fact, Nadine found her ability to serve as a deliberate confidant in those instances to be as rewarding for her as they were for her patients. She said, "It's rewarding to hear them say, 'I appreciate you calling. I'm feeling better because of what you told me. I've a new outlook on life because of this.' For me, the reward is leaving somebody better than you found them."

Clinical educators as deliberate confidants. A deliberate confidant is an individual who purposefully solicits and receives personal information as a means for providing coaching and counseling (Petronio, 2002). Unlike the stakeholder confidant, the deliberate confidant role expands beyond the medical context to include any individual who actively solicits and/or receives disclosed information for the purpose of advising, coaching, or counseling (Petronio, 2002). As evident in this study's data, the clinical educator role frequently involved the exchange of information to coach and counsel the patient in ways not just related to clinical outcomes or therapeutic advancements. Additionally, educators were able to establish solid, trustworthy relationships with patients that nurtured unfettered disclosures for reasons beyond their clinical credentials or perceptions that they functioned as surrogate HCPs. For these reasons, pharmaceutical-sponsored clinical educators served as deliberate confidants as well as stakeholder confidants. This section examines how educators functioned as deliberate confidants. Specially, two provisions are explored that exemplify why educators were able to take on the deliberate confidant role. These include the provision of access and time and the provision of reciprocating self-disclosures.

Educators spoke frequently of their role in soliciting, receiving, and managing personal and sensitive disclosures. In fact, the disclosed information typically went beyond the clinical components of the disease journey. Educators used words like "sensitive" to express the qualitative nature of the engagement and the connectedness that arose from their deliberate confidant status. Bonnie, an educator for numerous chronic conditions reflected on the nature of sensitivity in her patient experiences. She said, "I mean it's sensitive information, it's your health, it's very personal. I just think that maybe we're a little bit more aware of, that we do that. So, privacy, it definitely impacts the conversation…It's sensitive because it's just so personal." Tabitha highlighted how educating patients on self-injection often created an intimate environment because she was asking patients to expose parts of their body to her. She stated, "When you're teaching somebody, especially the one-on-one patients, that relationship becomes intimate very quickly. I mean we're teaching them how to inject and they're lifting up their shirts and we're telling them, 'It's okay, you're gonna do great.'"

Educators believed that, because they established an environment that valued the private and intimate nature of patients' personal disclosures, patients were more likely to divulge sensitive health information. Antonia, an educator for a terminal neurodegenerative condition, put it this way, "So, in a clinic setting or in a home setting, typically you can give privacy, but I often have patients tell me things in confidence that they would not say if somebody else were present." In fact, educators often created such a safe and comfortable setting for disclosure that patients would sometimes disclose personal health-related information they had not even shared with their physician. Cora, an educator for many different conditions, shared one such example. She stated,

> [Patients] would ask some pretty personal questions. But I think they felt like that was an open forum, and a lot of them just...they were personal in nature like erectile dysfunction. They hadn't talked to their doctor about it. I came against that all the time because it's like they're embarrassed to talk to their doctor about it...It's like they almost just needed someone to say, "It's okay to talk about it." I think that brought them a lot of relief.

Providing access and time. Ease of access was a factor that allowed educators to take on the deliberate confidant role. Bonnie, a telephonic educator for multiple conditions, believed that her ability to provide time to listen was one of the reasons patients disclosed that amount and type of personal information she frequently received. She stated, "One of the things I say is, 'If you sit down in a patient's room for three minutes, you'll be shocked what they will tell you.' …But I feel people will tell us anything if we give them the opportunity." Hanna echoed this belief explaining how her in-home patient education experiences often included receiving information that, though not always clinically relevant, provided an overall snapshot of the patient's life. She attributed this phenomenon to the fact that she gives patients her time. She stated, "I let them know my time belongs to them…We've gotten to the point where we've laughed, been offered something to eat, met the dog, husband, found out they love Santa Fe…As you have that discourse, you find out so much."

After sharing numerous examples of the ease by which patients disclosed voluminous amounts of personal information, Felicia, an osteoporosis educator, was asked why her patients seemed so willing to divulge their life stories to her. She attributed their actions to simply the fact that she was there to sit and listen. She stated,

"I sit and listen. The other day, I got up and I had to hug the woman because she started crying, telling me about the death of her daughter. I don't know, I sit and listen." Xoe, a diabetes educator, articulated a similar idea. She felt that the type of disclosure relationships she created by giving patients her time allowed her to gain more accurate insights toward clinically relevant behaviors such as medication non-adherence. She explained,

> I'm amazed at what patients tell the physician, and then what they tell us when we have an hour with them. You say, "Well, tell me why your blood sugars are out of control. What's going on in your life?" Maybe you found out that they had an extra bill, and they had to get the car fixed, so they didn't pick up their medicine. It's not that they're non-compliant, it's that life got in the way.

Ursula, a diabetes educator, believed that the time she invested with patients was not only rewarding to them, it also brought her a sense of meaning and professional fulfillment. She reflected, "You know, you get to close a door and yeah, you're really busy, but for that hour or whatever time you're spending with the patient, there's nothing else going on. It's just you and that patient. And it's so special."

Educators who delivered engagements in patients' homes felt that setting was another unique element of their role that afforded them both time and an opportunity to establish the type of relationships more indicative of the deliberate confidant. Felicia, an osteoporosis educator, reflected on this notion when she stated, "I have a different relationship because I've been in their home. I've met family members, their pets, I've heard their story. It's different from the doctor's office and he's in and out quickly, where I've actually been in their home." Gabi, who had also provided chronic disease education

in the home, felt the nature of that environment as a comfortable and safe space allowed her to better establish the type of personal connection inherent in the deliberate confidant role. She shared, "It's a huge bonus to go into the patient home and sit with them. It's a great value add because they feel comfortable and I think they feel safer with the treatment. Just knowing, having that personal touch with them."

Expectations for reciprocation. One hallmark of the deliberate confidant role noted by Petronio (2002) includes an expectation of reciprocating disclosures. She points outs that, in the instance of the therapist-patient relationship, this may sometimes prove problematic as therapists might alter their communication strategies if they believe patients have reciprocating expectations. During the interviews, few educators spoke of patients having expectations to receive personal information from them as a condition of the engagement. In fact, Nadine, a telephonic educator for chronic autoimmune conditions, was the only participant who provided a detailed example of such a request. She described, "I've had one or two cases, they were men, where they wanted me to share my information. They'd say, 'You called and asked me all these questions. Now I want to ask you questions and you're not gonna tell me?'" Nadine went on to explain how she was able to navigate around the request by deferring to her network's compliance policy that stipulated educators were not permitted to share personal information with patients. She described the way she responded when asked by a patient for her last name, "But as far as my information, I will just tell them that we are told that we're not to give our last name." Nadine appreciated this policy as she felt it was necessary to protect her and her identity. However, her actions also support Petronio's contention that reciprocity expectations can alter the communication dynamics between a therapist and patient.

Nadine, who lived in the Midwest, exemplified this notion when she stated, "One gentleman, I told him that I lived in Georgia because he was really creepy…just not something that I'm comfortable with…I put a note in the chart, and just kind of let everybody know not to talk to him."

Aside from Nadine, only two other educators, Martin and Hanna, discussed the concept of reciprocating disclosures. However, both spoke of it in the context of proactive actions necessary for furthering patient engagement as opposed to reactive measures provoked from patient requests. Martin was a diabetes educator who also had Type 1 diabetes for most of his life. He believed that his disclosure of his condition to the patients he taught improved their level of interaction and understanding. In fact, he admitted to conducting his own informal comparative experiment in group education classes in which he assessed patients' responses to not receiving or receiving that personal disclosure. The latter approach was more successful. He explained it this way, "I did my own personal experiment where I'd start a class and not tell them and then give a class and tell them right up front I've got diabetes. I'd see a totally different level of interaction, alertness, understanding." Martin went on to explain that because he became known by the diabetes community in his local area as someone who shared their disease, newly diagnosed patients would often request to be in his classes. He stated, "I've had patients tell me, 'I want you because you have diabetes, and the other ones don't.'" In Martin's view, patients saw value in the opportunity to learn about diabetes self-management from someone with that shared experience.

However, Martin also pointed out that patients were sometimes surprised by his response to their self-management disclosures. Though he was empathetic to the

challenges of diabetes, Martin was often unsympathetic to self-pity or unreasonable excuses for improper or non-adherent behaviors, having overcome his own challenges with the condition. He shared, "The doctor I worked with didn't have diabetes. I'd tell [patients], 'He's probably a lot more sympathetic, pampering-petting than me. I've lived through a life of going to college, getting three degrees, with diabetes. I know it can be done.'"

Hanna, an educator for both diabetes and osteoporosis, also spoke at length about the notion of reciprocating disclosures. She shared Martin's view that proactive personal admissions of health struggles can motivate patients to be more active with discussing disease self-management behaviors. She provided the example of how she would share her own struggles of sticking to a diet when discussing that topic with her diabetes patients. She stated, "If you're talking about changing dietary patterns, it's more humanizing to say, 'I know this is difficult. I've had issues with this myself.' In the sense that, you're not perfect, and it's not one of those 'Do as I say…'" Hanna believed that these sorts of self-disclosures served a purpose as they helped assure patients she was non-judgmental in her interpretation of their journey. She put it this way, "I think something else that, once again, feeds into that is that self-disclosure as the educator. That patient needs to know that you are non-judgmental, and a lot of times that will come through with some self-disclosure."

Hanna's insightfulness toward the purpose and potential of her personal disclosures had been prevalent throughout her interview. She had expressed earlier a belief that impactful disclosures needed to occur with appropriate timing during the engagement. She felt that her delivery of a self-disclosure was contingent upon receiving

an invitation for it from the patient. That invitation could only come after a patient had the opportunity to share their story and their experience of the disease journey. She reflected,

> I have learned over 30 years of doing all this that everybody has a story, and they have to tell their story first. Not only does it give you the background that you need, but they need to tell you. I mean, it is an absolute necessity that they tell you their story. I don't know what to say that accounts for that, but I just witnessed it so frequent. Then, once they get their story told, it's almost as though you are then being given permission to disclose some things about yourself, which is another one of those bricks for the foundation for building that rapport.

Clinical educators as reluctant confidants. A reluctant confidant is defined as someone who is disclosed information without an expectation or need for that disclosure. For instance, an individual who randomly receives private unexpected information from a stranger is a reluctant confidant (Petronio, 2000). Petronio also points out though that a deliberate confidant can become a reluctant confidant when they are provided more information than they want or need to know. The educators for this study shared numerous examples of experiences that are representative of a reluctant confidant role. In fact, for educators who delivered multiple touchpoint programs, those situations were quite common. One reason for this phenomenon is that, as trust builds throughout the intervention relationship, so does the potential for the patient to reveal personal disclosures unrelated to the therapeutic goals of the program. The remainder of this theme examines educators experiences as reluctant confidant and includes descriptions of strategies they used to manage or deflect unwanted or irrelevant disclosures.

As evident throughout the interviews, educators felt they were frequently on the receiving end of extraneous and irrelevant information disclosed by patients. Deandra, who provided in-home education for patients with chronic conditions and rare diseases, summarized this phenomenon this way, "When you're sitting in their home with them for a couple of hours and you're doing this every week for a couple of weeks, yeah, you can get into some really interesting conversations." Gabi, another in-home educator for multiple disease types, went as far as to admit that the disclosures were sometimes so unusual or surreal, they seemed contrived. Though she did not provide any specific examples, she jokingly explained, "I sometimes wonder when I go into a home, I'm like, 'Am I on Candid Camera or something?' Sometimes I'm like 'Is this real? I can't believe it, are they testing me?'" Later in her interview, Deandra went on to rationalize that, regardless of the information that was disclosed, she felt it was her duty to listen. She believed that receiving extraneous information had a purpose, if for no other reason than serving as a type of therapeutic release for the patient. She stated, "You put your eyeballs back in your head and sit and let them tell you because they obviously feel comfortable and there's a reason they're telling you. It's usually a therapeutic thing for them to be able to tell somebody." Antonia found this interpretation also relevant for her terminal neurodegenerative disease patients. She understood that the despairing nature of their condition could often lead them to haphazardly share information with little relevance to their therapy. She stated, "Patients that are terminal are desperate and they're desperate for someone to understand them. And for someone too, this is a very rare disease. And they'll tell you things that you would never chart."

Felicia was an educator who joyfully shared numerous stories and anecdotes about her experiences as a reluctant confidant. She delivered training for an osteoporosis medication in an area of the country known for having an affluent population of retired and widowed women. She affectionately referred to her patients as "my little old ladies" and took great pleasure in engaging them in conversations during her product training sessions. She felt that many of her patients equally enjoyed her company as they would freely disclose information about themselves. She put it this way, "Oh, God. Well, most of the patients, if I could stay there for hours, they would tell me their entire life story." She continued by offering examples of the various non-therapy-related topics patients would broach and how those conversations have even given way to invitations to join them for social outings. She shared "I've heard about children's death, divorce, cheating husband, woman followed her husband to the car dealership and caught him with this girl. It's amazing! I've been invited to go for drinks with a group of 75-year-old women looking for men." Felicia later admitted that, while such socially enriching experiences made her job enjoyable, they also made it challenging from a time management perspective. She noted, "My first osteoporosis patient was a two-hour visit. She told me about her husband, the divorce, the girlfriend, the this, the that. I walked out going, 'I'm not going to get any work done if every visit is like this.'"

Petronio (2002) explained that professions such as nurses fall into a subset of reluctant confidants she referred to as occupational confidants. These are individuals who are frequently disclosed extraneous or unsolicited information as a result of their occupation. Other examples include bartenders and hair stylists. She states that, while many of these individuals tend to recognize their occupation predisposes them to

receiving unwanted information, they still use strategies to curtail or deflect that sort of information. Such was the case with clinical educators. In fact, a few educators shared the tactics they used to mitigate or control unwanted disclosures when placed in a reluctant confidant role. Hanna, a diabetes and osteoporosis educator, believed that educators should be careful in not dismissing or ignoring disclosed extraneous information. She felt it was important to accept and listen to all of what the patient was sharing, as not doing so was a discredit to the patient. She stated, "To be dismissive of them, and/or to not give them your time, I think is a discredit, not only to being a provider, but I think it's also very insulting."

Other educators, however, felt there were tactful ways to address a derailed conversation without endangering trust or appearing dismissive. Gabi, an educator for multiple disease types, explained that her approach is a gentle redirection back to the topic at hand, what she referred to as "bringing them back onboard". She put it this way, "You just roll with it, if it's not pertinent to their training…I bring them back to what we were there to discuss. It's just experience...talking with patients, you just bring them back onboard." Nadine, an educator for patients with chronic autoimmune diseases, offered a similar strategy, noting how redirecting the conversation can sometimes require creative nuancing. She shared, "You got to find balance between allowing the patient to talk about what they want to talk about, but also redirecting the focus of the task at hand. You got to be creative and know when it's safe to break."

One educator, Olivia, believed that in some instances, an educator may need to simply shut down unwanted disclosures if they become a distraction or seem disingenuous to the goal of the engagement. She shared an example of a patient who

disclosed repeatedly that she was using recreational marijuana while taking the drug on which Olivia was training. The patient continued to broach the topic to the point Olivia felt the patient was simply trying to goad a disapproving reaction from her. She explained that she eventually put a hard stop to the situation by stating the following to the patient, "I'm not going to comment on that as a nursing professional. Our package insert doesn't speak to using marijuana with this medication, and I'm done talking about this.' Sometimes you just have to put it out on Front Street."

Summary of Findings

Educators viewed trust as foundational to their relationships with patients. It was necessary for soliciting the types and quality of disclosures that enabled them to effectively coach patients to behavior changes. When discussing the concept of trust in their role, many educators interpreted its meaning within the context of rapport. Some believed the terms to be synonymous while others felt one was predicated upon the other. Regardless, most educators believed they benefited from a predisposed high level of trust automatically imbued to them by patients because of their healthcare credentials.

Educators shared that it was important to establish trust at the start of their relationship by reassuring patients they had their best interest at heart. Some educators even felt it appropriate to disclose personal anecdotes related to their role. Once trust was established, educators engaged in strategies to maintain it, especially for patients enrolled in multiple engagement programs. Some educators noted how the mere fact they were accessible and available to provide time for coaching was a trust-strengthening factor; physician inaccessibility was a common criticism of patients. Giving patients their time and an attentive ear also included allowing patients the opportunity to share their story

and their disease journey—a concept educators noted as an effective trust-strengthening tactic. Along with accessibility, educators noted that it was important to present a demeanor of honesty along with a non-judgmental attitude. Educators placed a high value on maintaining trust as they recognized the potential devastating impact of a trust loss on their credibility and on patient outcomes. They believed a disruption of trust could stymie comprehension and impede achievement of disease self-management goals.

When asked during their interviews how they interpreted the concept of privacy within the context of their role, educators often shared thoughts about the way their patient disclosed health information to families, friends, and others. According to the educators, these disclosure strategies were diverse with some patients not even sharing their disease diagnosis with spouses or other immediate family members. The other way educators addressed the notion of privacy was through descriptions of the disclosure expectations placed upon them by patients and by themselves. In all these cases, educators highlighted a range of privacy rules used by themselves and patients to manage when, where, why, how, and to whom information was shared. These rules fell into two CPM privacy rules management categories, routinized and changing. The routinized rules were dictated by stable, non-changing criteria called core criteria while changing rules were dynamic, situationally based and managed by catalyst rule criteria.

The routinized and changing rules educators used to manage their own disclosure behaviors regarding patient information were examined within the context of three influential parameters. The first parameter was professional ethics which described how educators adopted privacy management strategies based on the ethics that oriented them during their experiences working as a field clinician. The second parameter was the

political/legal ecological context. This construct examined how compliance and regulatory factors described in Chapter 4 were influential in the development of the routinized rules used for managing patients' private information. The final parameter was insights garnered from patients' privacy management behaviors. The knowledge educators gained from their observations of the way patients managed privacy with family, friends, and others, influenced the core and catalyst criteria educators used for developing and utilizing privacy rules.

Patients' expectations of the way their disclosures were managed by educators were dependent on the type of confidant role they co-constructed with those educators. For this study, three CPM confidant roles—stakeholder, deliberate, and reluctant—were relevant. Patients often freely disclosed information to educators because they saw the educators as a stakeholder confidant in their care. As such, patients understood disclosure was necessary to receive care. Patients also trusted the educators would manage their private health information because of the professional and ethical obligations inherent to their field.

Clinical educators undertook a deliberate confidant role meaning that patients expected to disclose information to educators because of the educators' roles as coaches and counselors. In return, educators recognized that they needed to make certain provisions for patients. One provision was trust; patients needed to feel they could trust their educator. Next, educators needed to provide patients with an outlet for sharing as well as access and time. Finally, a few educators noted the appropriateness of providing reciprocating self-disclosures. This included self-disclosures that were reactive and in response to patient requests as well as proactive measures used to motivate and reassure.

Educators frequently assumed a role of a reluctant confidant—an individual who receives disclosures without an expectation for such. As most of the educators in this study delivered programs that included multiple engagements with each patient, the educators were often on the receiving end of extraneous or irrelevant information. While such disclosures possessed the potential to derail the educator-patient dynamic, most educators were able to mitigate impact through deflection strategies.

The next chapter will discuss what these findings mean within the context of the two theoretical frameworks as well as the implications they have for the policies and regulations that manage the way educators communicate with patients. That chapter will also include an explanation of the limitations of this study as well as opportunities for future studies that can address those limitations.

Chapter 6: Discussion

In this chapter, I discuss the conclusions and implications of the findings outlined in the previous two chapters. The goal of this chapter is to understand how the identified themes are supportive of, and operate within, the two theoretical frameworks that guided and extended the study. Those frameworks are the ecological model of communication in the medical encounter (Street, 2003) and communication privacy management (CPM) theory (Petronio, 2002). The chapter is organized by sections corresponding to each of the seven themes identified in the Findings chapters. Each section explores conclusions that can be made about the theme as it related to the theoretical framework/s. The practical implications of those conclusions then follow. The chapter ends with an explanation of limitations of the study as well as potential areas and ideas for future research. A short narrative of final thoughts closes the chapter and the study.

Conclusions and Implications of Themes 1 and 2

Theme 1 states, "Political/legal contexts factors, manifested in pharmaceutical industries' compliance regulations, greatly influenced clinical educators' communication with patients." Theme 2 states, "The influence of ecological factors, particularly within the political/legal context, would frequently force educators to experience ethical dilemmas."

Conclusions of theme 1. Educators were keenly aware of the unique legal implications of their job and how their responsibilities exposed them to liabilities not experienced by most healthcare providers (HCPs) or other roles within the pharmaceutical industry. The looming threat of legal repercussions resulting from their actions served as a highly influential, if not *the* most influential, ecological factor in

determining the way they engaged with their patients. One educator's quip of "Not only do we practice medicine, but we practice law" captured that realization succinctly. Educators spoke repeatedly of the litigiously minded nature of their employers. In fact, some educators believed the pressure to remain constantly vigilant to the industry's legal parameters and regulatory expectations went as far as to spawn feelings of paranoia. Other educators were more sympathetic to the industry's intense focus on liability protection by focusing culpability on the aggressive government regulators who oversaw them. For instance, one educator's comparison of the U.S. Food and Drug Administration (FDA) to "vipers" who would attack any company not perceived to be towing the compliance line was emblematic of that view. Regardless, educators understood that the political/legal ecological factors inherent to their role had high-stakes monetary implications in the form of government fines and court settlements. Unfortunately, the legal ramifications related to the clinical educator role had a heavy impact on the communication dynamics between patients and educators. The remainder of this section examines such conclusions and implications.

Educators recognized that government agencies create compliance regulations to protect the public's health and ensure the safe and accurate distribution and promotion of prescription medication. Additionally, educators understood that, for their employers, compliance regulations served first and foremost as a means for managing the liability risks inherent to their industry. Still, for most of the interviewed educators, the influence of political/legal context factors, such as compliance regulations, functioned as a type of communication constraint and thereby, also a source of frustration. This study identified three types of compliance regulations that served as the primary factors of

communication influence— adverse event (AE) reporting, staying on-label, and fair-balance presentation.

Many of the conclusions and implications that arise from these three influences are reflective of assertions noted in Street's (2003) ecological model. For instance, he hypothesized that the impact of health system regulations and managed care policies (two organizational context factors), coupled with the fear of litigation imposed by health insurers, forced some physicians to use a more cautious or guarded style of conversation with their patients. Further, that physician-centered communication style functioned in a manner that Street considered a predispositional influence. Predispositional influences, along with cognitive-affective influences, are the two categories of interpersonal contexts that operate in the center of Street's ecological model and are inherent to both patients and HCPs. Interpersonal context factors, such as communication styles, are often outcomes that result from the influence of other ecological factors such as age, gender, or personal finances as well as internalized attributes such as personality or self-efficacy perceptions.

Emanuel and Emanuel's four models of physician-patient relationship (1992) provides further perspective on the nature of communication styles as it relates to Street's (2003) ecological model. The authors identified four models of interpersonal health communication processes that have frequently been applied within the context of shared medical decision making. Though Emanuel and Emanuel focused on the physician role, the constructs of model type and shared decision making has been studied with other types of HCPs, including nurses (Friesen-Storms et al., 2015; Stacey et al., 2008). While Emanuel and Emanuel identify four models, only two are relevant to the present study.

In the *paternalistic* model, the physician emphasizes the patient's well-being over the patient's need for autonomy and thereby determines for the patient what is in their best interest. The physician does this because of their belief that that patient's values are the same as their own and therefore do not need to be solicited from the patient. Since this model engenders the HCP as the decision maker, it would not be reflective of the pharmaceutical clinical educator role given that educators are legally prohibited from providing medical advice, yet alone making medical decisions. The *informative* model, which the authors note is akin to Rotor and Hall's (1992) *consumerism* model, is the inverse of the paternalistic model. Here, the patient's values are clearly defined and articulated, and there is no need or place for the provider's values. The patient is simply in need of the facts from the physician, who takes on the role of a technical advisor. The third model is identified as the *interpretive* model which posits that the role of the HCP is to provide technical information to patients as well as to elucidate values regarding proposed therapies and medical decisions. Ultimately though, the patient still maintains autonomy for decision making and determines whose values will guide treatment. The interpretive model is different from Emanuel and Emanuel's fourth model, the *deliberative model*. For this model, the HCP not only empowers the patient with both technical knowledge and values, he or she also helps the patient make medical decisions. Like the paternalistic model, the deliberative model would be outside of the pharmaceutical clinical educator scope as educators cannot provide any sort of medical advice or clinical assistance.

When observed within the context of the role of the pharmaceutical-sponsored clinical educator, two of these models become relevant, the informative and the

interpretive. For the most part, the interview data suggested that most clinical educators idealized a deliberative model, particularly as a communication approach for their clinical field experiences. However, given their recognition of their limitations for providing medical advice, educators strove to utilize an interpretive style of communication. Emanuel and Emanuel (1992) equated the HCP's role in this model as a counselor or advisor whose purpose is to assist a patient in identifying and articulating his or her values regarding the management of their health. Educators frequent refrain of "meeting the patient where they are at" was, among many articulated strategies, indicative of how theirs views were supportive of the interpretive model. Educators saw themselves as coaches, counselors, and advisors.

Interestingly though, while most educators endeavored to engage patients using a communication style aligned to tenets of the interpretive model many of them found themselves forced to adopt an approach reflective of the informative model. As Emanuel and Emanuel (1992) note, this communication style is characterized by HCPs whose purpose is simply to deliver information about the disease state, treatment options, and related risks without any imposition of values; they described an HCP in this model as a technical advisor. Educators' attitudes were such that this was the preferred model of pharmaceutical companies and government regulators, given the industry's stringent focus on liability protection. Even more so, the nature of the compliance regulations themselves provoked a level of influence that many educators felt left little option for a communication style other than the informative one. Hence, educators' beliefs provide validation for Street's (2003) assertion that organizational context factors, such as managed care systems, force physicians to adopt a communication approach that limits

patient engagement. The following section interprets how the political/legal context factor of adverse event reporting, staying on-label, and fair-balance presentation functioned in a comparable manner and similarly created limitations and barriers for educators' preferred communication style.

Interpretation of the adverse events factor. Unlike pharmaceutical sales representatives who may receive an AE report from a physician, educators are unique in the industry because their role predisposes them to receiving a high volume of AE reports directly from the primary source, the patient. However, unlike their prior positions as field clinicians in which AE reporting was voluntary, the pharmaceutical educator role mandates they capture and report *any* side effect or reaction that could be perceived to be an adverse event. This proved problematic for educators who noted that collecting AE data from patients was a time-consuming endeavor given the required scope and detail of requested information. Ultimately, AE documentation stole minutes from the already limited amount of time educators were afforded to engage the patient in education and behavior change management conversations.

In general, the current AE documentation process required by the FDA which places a mandatory collection onus on drug manufacturers, has been described as taxing and inefficient (Moore et al., 2015; Silverman, 2016; Thomas, 2015). This is because, apart from clinical educators, most company-based reports originate from secondary sources, such as sales representatives receiving information about an incident during a physician's office visit. Hence, the information provided by the industry to the FDA is often limited or incomplete (Moore et al., 2015). Adding to the issue is that the FDA rarely receives reports directly from patients. Criticisms leveraged at the FDA have also

suggested that field-based clinicians, who are voluntary reporters, are more likely to possess the type of comprehensive information about new or previously unreported AEs that produce the most accurate safety data (Moore et al., 2015). As multiple educators from this study noted, many of the AEs they collect are already known side effects or reactions, yet they must still report each instance. This requirement can directly impact communication dynamics. Additionally, educators described how the use of common clinical conversation starters such as "How are you doing today?" were discouraged as they could facilitate a response that includes a reportable event, even if it seems unrelated to the medication.

My own experience developing program materials and telephonic call guides would validate how the industry's desire for mitigating AE reports impacted educators' communication approaches. During a meeting with one of my pharmaceutical client's Medical Legal Regulatory (MLR) team, an internal division responsible for reviewing educational and public-facing media and materials for medical accuracy and regulatory compliance, a draft program guide was being evaluated for approval for use. Members of the MLR team requested that I remove a line at the start of an instructional guide for educators that directed them to greet the patient with, what I assumed at the time to be an innocuous statement such as "How are you doing today?" The rationale for the removal, as stated by the MLR team, was that such a statement could trigger the type of disclosures that, even if unlikely to be related to the use of the medication, would be considered reportable AEs. This example illustrates how a common trust-building greeting used frequently in field-based clinical encounters was subject to veto in a pharmaceutical-sponsored education engagement. Hence, a universal strategy that

educators could use to help build trust was stymied. Additionally, from a theoretical perspective, the industry's aversion toward the use of conversational pleasantries out of fear for prompting AEs is revealing of its preference for an informative style of interpersonal communication (Emanuel & Emanuel, 1992). Unfortunately, though, such behavior by pharmaceutical companies may inadvertently prevent educators from engaging with patients in a communication style to which they value and are most accustomed.

AE disclosures can be problematic to the educator-patient relationship in other ways. Though AE reports submitted to the FDA by pharmaceutical companies are generally not considered admissible in civil litigation cases (Beck, 2010), other documents or notes written by educators about patients and their health could be considered discoverable evidence. Hence, this is the reason why most pharmaceutical companies have a policy against educators keeping notes about their patients, such as the regulation described by an educator in Chapter 4. The primary concern is that, if an educator records any information that could be perceived as an adverse event but then does not report that information through proper FDA channels, the company could face legal repercussions and the AE information could potentially be included as evidence in civil court cases.

The detrimental influences related to AE reporting requirements should not be misconstrued as an argument against the necessity for educators to properly solicit and collect them. In fact, there is a theoretical precedent that illustrates why actively encouraging a patient to disclose treatment status, including unforeseen reactions, is supportive of better long-term health outcomes (Cegala, 2011). However, the industry

needs to understand that such patient disclosures are more likely to happen when an educator embraces a type of communication style that encourages a shared values approach. Cegala found that communication styles that promote collaboration in the medical encounter (i.e. characteristics of the interpretive and deliberative model), tend to result in patients reporting more detailed information about their disease and therapy responses. As he goes on to point out, this is important as studies have shown that up to 80% of decisions an HCP makes about diagnosis and treatment is based on the information patients disclose about their condition, with the remaining information coming from laboratory tests and other assessment measures (Frederikson, 1995; Peterson et al., 1992). Though educators are not able to make medical decisions based on AE reports, they do have a responsibility to ensure their patients' physicians are made aware of AEs. Hence, educators who engage with patients in a coaching or counseling capacity, as opposed to acting as merely a purveyor of technical information, will be more likely to receive AEs which, once shared with the physician, may result in a better and more precise treatment for the patient.

Educators raised legitimate concerns regarding the burdensome nature of excessive and unnecessary AE reporting that can adversely impact their programs' intended clinical and behavioral outcomes. When the documentation process becomes so onerous it shortens the time educators can spend engaging patients in fruitful conversations, patient comprehension of information can suffer. When educators are advised to avoid using empathy-building communication pleasantries for fear of sparking an AE, trust bonds can be weakened. When educators are denied the ability to document the type of patient information that allows them to nurture meaningful and tailored

conversations, disease journey navigation becomes more difficult. While the legal and liability rationales for AE reporting are apparent, their unintended consequences need to be given greater consideration by the industry and regulators lest they undermine the ability to fully protect patients.

Interpretation of the staying on-label factor. Like AE reporting, educators understood the rationale for maintaining on-label compliance though noting that it often adversely influenced their communication with patients. While program scripts and instructional guides provided the roadmaps for delivering consistent-with-label content, patients who posed off-label questions created challenges. Of notable frustration were those situations in which educators knew the answer to an off-label question but were obligated to defer the patient back to their physician or to another resource. This was one area in which some educators highlighted a clear disadvantage of the pharmaceutical educator role compared to their field clinician role—where engaging in off-label discussions was typically permissible.

In addition to inconveniencing the patient, educators believed that this requirement left patients skeptical of educators' capabilities or would force patients to question the legitimacy of their role. Even more so, educators seemed most concerned that their inability to address off-label questions could have repercussion for patients' comprehension of information. As discussed in the findings, concerns with staying on-label were not always related to questions posed reactively by patients. Physicians can prescribe a drug for a different indication or dosing regimen than what is stated in the prescribing information (PI). Both instances are considered "off-label uses" (U.S. Food & Drug Administration, 2019). As such, this introduces a unique communication

challenge as educators must train those patients using language and materials containing content that does not address, or potentially conflicts with, the information or statements provided by the physician. Adding to that challenge is that, because of the requirement to stay on-label, educators cannot adjust the delivery of the content to account for such differences nor address patient questions regarding those conflicts beyond deferring the inquiry back to the prescriber. Should a patient ask whether their off-label dosing regimen changes the likelihood or severity of side-effects, an educator, whose academic training or prior field experiences may have provided them the knowledge to accurately address the question, would still need to defer the patient back to their physician for the answer.

Educators are expected to stay on-label because, like mandatory AE reporting, regulators consider such actions necessary to safeguard patients and the industry sees it as another layer of liability protection. As multiple educators pointed out though, many patients quickly establish strong trust and communication bonds by virtue of an educator's nursing credentials and the fact educators are more likely to spend the sort of time engaging patients in the types of meaningful conversations that are absent in physician encounters. Additionally, as educators also noted, some patients are intimidated with raising questions with their physician that could be perceived by the physician as a challenge to his or her authority or expertise. Hence, when an educator defers an off-label question to which they know the answer, trust bonds can be eroded. Secondly, patients are at risk of never receiving the information if they are uncomfortable discussing the topic with their doctor. Together, these two outcomes have the potential to

adversely impact patients' understanding of the rationale or benefits of treatment and subsequently hamper their ability to properly self-manage their disease.

An educator's off-label response is typically a reactive issue. For the most part, such problems arise only after a patient asks a question or poses a concern that requires the educator to reply. An interesting paradox is that those educators who adopt a communication style in the spirit of the interpretative model are at higher risk for receiving off-label questions than those educators who embrace a style characteristic of the informative model. As Street (2003) and Cegala (2011) made clear, HCPs who employ a collaborative communication style tend to receive a higher degree of participation from patients, including receiving more thoughtful and relevant questions. At the same time, when an educator defers off-label questions back to a patient's HCP, a perception of dismissiveness may erode trust and thereby stymie a collaborative environment. Fortunately, as will be discussed later in this chapter, educators utilized other communication strategies to moderate the impact of off-label deferring and therefore, safeguarded trust bonds.

Interpretation of the fair-balance presentation factor. Multiple educators euphemistically summarized the concept of fair-balance presentation as the requirement to give patients "the good, the bad, and the ugly," an acknowledgement of their mandate to address difficult topics such as black box warnings and other side effects in addition to a product's efficacy and benefits. Interestingly, educators did not begrudge their obligation to share risks and potential consequences of a medication. In fact, they viewed doing so as a requisite strategy necessary to ensure patient autonomy, a concept discussed later in this chapter. For most of the educators, their primary criticism of this factor was

how it manifested itself via overly structured program expectations and inflexible materials and instructional processes. Many pharmaceutical companies sought to control the fair-balance message, and ensure liability protection, by producing call scripts, instructor guides, and presentation media that left little to no option for customization to specific patient needs or learning situations.

Not surprisingly, educators tended to focus their ire on these types of programs, expressing that their inflexibility devalued educators' clinical and communication skills. While the logic for highly structured programs mirrored the rationales for AE reporting and staying on-label (i.e., patient safety and legal protection), they similarly had unintended consequences with the potential to undermine their primary intent. One concern articulated by numerous educators was that rigid program delivery requirements could not account for the diversity of health literacy levels, comprehension skills, or language barriers of an entire patient population. Hence, large segments of the intended audience would not comprehend the programs if presented as expected. Not only did program inflexibility prevent educators from adapting the word choice or language style to a patient's perceived literacy level, some noted that it impeded their ability to evenly properly assess whether a patient was understanding, or being engaged by, the content.

While educators did not speak of this issue in socio-ecological parlance, they did interpret it within the primary constructs of Street's (2003) ecological model. For example, ecological scholars contend patients' communication capability and style are uniquely related to the context factors that define their personal characteristics (i.e. highly educated patients tend to ask more questions than their less educated counterparts, more worried patients articulate more concerns) (Cegala, 2011; Street et al., 2005, 2012).

Educators similarly recognized this relationship and, as most were proponents of an interpretive style of interpersonal communication, they sought to engage patients in ways that aligned to their educational and affective levels. In other words, educators understood that when they can adapt their language and delivery tactics to patients' preferred learning styles and literacy levels, not only were patients more likely to comprehend the program content, they are also more likely to engage in active participation behaviors such as asking questions and setting health goals. Additionally, as studies on communication competence would note, compliance regulations could actually function to constrain an educator's communication skills (Spitzberg & Cupach, 1989). Therefore, educators become a less competent communicator and potentially less likely to utilize share decision-making strategies

A few educators hypothesized that part of the problem with stringent and inflexible programs was that they were designed by the pharmaceutical companies' marketing teams instead of professionals with a background and expertise in health literacy, adult learning principles, and patient education. One educator's rhetorical question of "Do you want an architect or a chef to design your kitchen?" captured the essence of the belief that the manufacturers of a drug are not necessarily the best entities to design the approach for teaching patients how to use it. Given my responsibilities as a program designer and content developer for VMS, I can provide relevant insight for this topic. While I cannot attest to how other patient support services' companies approached development, the process for creating clinical educator programming and materials at VMS was typically a collaborative effort between the client's brand management team and VMS' creative services and account management divisions. I worked within VMS'

creative services department. Another frequent contributor was the client's agency of record (AOR), which is a third-party marketing or advertising firm responsible for developing and managing the client's entire brand strategy, marketing and media artifacts, and promotional efforts.

Program development responsibilities were outlined as part of the contractual agreements between VMS and the client. However, the scope of influence among the three entities—VMS, the client, and the AOR—related to program design and development varied based on budgets, existing materials and resources, and the client's oversight tolerance and risk aversion levels. In my experience, those clients with an existing suite of patient support resources, along with a need for vigilant oversight and a high aversion to risk, tended to result in the types of highly structured, rigid programs that educators found most troublesome. On the other hand, those clients without existing patient support resources, or with little risk aversion and less need to engage in oversight, would result in programming that provided greater flexibility and freedom in the way it was delivered. Like the educators though, my program design strategies and content structure were ultimately accountable to the same compliance regulations and protocols within which they were required to work. Ideas I proposed for leveraging educators' communication skills more effectively, or tactics I sought to utilize to provide educators greater autonomy in content delivery, were often denied and removed during the MLR approval process. Hence, in many cases, the issue was not that the "architects" were not consulted for a best design, it was that the best design was not approved.

Like the educators in this study, my own personal belief regarding patient-educator interpersonal communication styles centered on approaches that promoted a

sharing of values and a high level of mutual engagement. In essence, my view was supportive of the interpretive model (Emanuel & Emanuel, 1992). Hence, whenever possible, I would incorporate in program design and delivery methodologies those educational tactics and engagement strategies that nurtured that style of communication. As Street (2003) concluded, patients and providers each have the potential to exert considerable influence over the behavior of the other. Therefore, both must cooperate and coordinate their responses to create a coherent and successful exchange. As the instructional designer, my idealized goal was to develop a program framework that fostered a balanced level of influence, while still staying within the compliance framework required by the client and regulatory agencies. Yet, as many educators surmised, such was a task that is easier said than done. I empathized with their concerns that highly scripted and inflexible programs forced them into the role of a "technical advisor", a characterization of the informative model. I understood that their frustration extended beyond how those programs devalued their professional expertise. For most educators, their concern was far less personal.

Educators warned that two serious implications of these types of programs were that they had the potential to exacerbate treatment failures and they could encourage patients to drop out before the program completed. Treatment failure was not predicted to be a direct effect of inflexible programs, but rather was the outcome from a progressive series of breakdowns. Treatment failure happened because the patient was not adherent to taking the medication as prescribed. Non-adherence was a result of them not understanding the information about the medication, which was a consequence of them not receiving the information in way that aligned to their comprehension level and

literacy skills. Thus, educators were reiterating many of the concerns noted in the literature about adherence issues (Briot et al., 2009; Hammond, 1995; Shu et al., 2009). Secondly, some educators felt that highly scripted programs forced them into an unnatural presentation and linguistic style that was perceived by patients as contrived or insincere. As a result, patients who were enrolled in programs with multiple engagements would simply stop attending midway through.

Conclusions of theme 2. Like the participant sample for this study, most of the healthcare professionals who provide pharmaceutical-sponsored clinical education come from nursing, a profession to which patients and the public offer high levels of respect. In fact, nurses are repeatedly ranked at the very top of annual public opinion surveys of the nation's most trustworthy careers, placing higher than physicians and pharmacists, because they are viewed as honest, of moral character, and committed to high ethical standards (Brenan, 2018; Reinhart, 2020; A. Stone, 2019). The participants for this study were aware of the sense of trust imbued upon them and often referenced it as a foundation of their professional and philosophical orientation. Throughout their interviews, they frequently articulated the high expectations by which they held themselves for maintaining that trust, even though their clinical educator role was outside of direct patient care.

Trust was fundamental to the educators' role from the perspective of the ecological model as well. In fact, Street (2003) provided insights that match the beliefs articulated by many educators. One insight was that an HCP's predispositional influences (i.e. their communication style and performance) have a direct bearing on level of trust given to the HCP by the patient. In the context of this study, that meant that

patients were more inclined to actively participate in an educator program in a manner that is characteristic of the interpretive model when there were high levels of trust.

Street (2003) continued by a describing the interrelated nature of trust, ecological factors, and the larger healthcare system—a relationship relevant to this study as well. As he explained, one drawback to the ecological influence of managed care programs is that trust in the entire healthcare industry itself can be put at risk. This happens when there is discontinuity of care caused by an employer changing health plans and thereby forcing a patient to sever a relationship with an established physician. When an established bond is forcibly broken between patient and physician by the healthcare system, a patient's trust in that system can abate until the patient establishes a new bond with a new physician.

Not surprisingly, the pharmaceutical industry was keen in its understanding that hiring highly trusted professionals was in their best interest for that same reason. By employing primarily nurses as clinical educators, pharmaceutical companies, an industry increasingly distrusted among the public (Bulik, 2018; Harris Poll, 2017; J. McCarthy, 2019), have capitalized on the profession's implied trustworthiness. Interviewed educators overwhelming stated they felt trusted by their patients. However, this was despite many educators believing their role has been increasingly handicapped and devalued by overly restrictive and counterproductive compliance regulations. In turn, that devaluation forced them to adopt interpersonal communication styles akin to that of a technical advisor.

This belief that their role is perceived by the industry as simply an information transmission conduit between two entities, the pharmaceutical company and the patient,

has similarly been noted in studies of other healthcare professionals, specifically medical interpreters (Hsieh, 2008). Those studies explored how medical interpreters, physicians, and other HCPs recognized medical interpreters as a utilitarian conduit role that was to be "robotic" and non-thinking. In essence, the primary function of the profession is to neutrally and faithfully convey information between the patient and HCP without influencing the content or dynamic between them (Hsieh et al., 2010; Hsieh & Kramer, 2012). Outcomes from those studies can inform the implications for this one. For example, in one study, a passive and utilitarian perception of the interpreter role by HCPs was noted to create interpersonal and ethical dilemmas with the power to compromise patient care because they pitted the needs of the patient against the needs of the provider (Hsieh & Kramer, 2012). Such ethical dilemmas are explored next.

Interpretation of ethical principles. One of the key takeaways from Theme 1 was that the influence of political/legal context factors, manifested in compliance regulations, often conflicted with educators' professional ethics and sense of duty to their patients. Additionally, many educators felt morally bound to do whatever was necessary to avoid breaching the trust they established with patients. For some educators, these attitudes prevailed over their obligation to deliver a compliant educational engagement. Hence, those educators chose to engage in purposeful non-compliant behaviors. In Chapter 4, three educators were profiled for being the most forthcoming in their disclosures of such actions. However, other educators intimated that they too had broached compliance protocols in the past or were amenable to doing so if an appropriate situation required it. While these educators engaged in different types of non-compliant actions, their rationales for doing so all centered on a deep-seeded moral and ethical

obligations that placed patient needs over employer expectations. In fact, educators frequently found themselves contending with internal struggles such as, "What do I do ethically? Where is my first responsibility? Is it to this patient or to this drug company?" Educators often addressed such questions within the framework of three medical ethics foundational to most HCPs' professional orientation—respect for autonomy, beneficence, and non-malfeasance (Beauchamp & Childress, 2013).

Medical ethics are critical factors for the patient-HCP communication dynamic. In fact, Duggan and Street (2015) contend that this relationship has been instrumental for society's fundamental shift from the biomedical model of medicine, which focused on disease pathology and a paternalistic communication style, toward a relationship-centered model. They noted, "Relationship-centered care values the individual characteristics and concerns of patients…and places moral value on the formation and maintenance of genuine provider-patient relationships" (p. 245).

Not surprisingly, the relationship between ethics and the patient-HCP communication dynamic has been interpreted within the context of multiple interpersonal health communication frameworks. However, in most communication models that explore this relationship, the medical ethic of respect for patient autonomy is often the singular or primary focus. For instance, Street (2003) explained that physician's respect for patient autonomy was often impeded by the physicians' obligations to the managed care system to which they were part. Such systems fell under Street's definition of an organizational context. Additionally, Emanuel and Emanuel's four models of the physician-patient relationship (1992) characterized the physician-patient relationship not as a power dynamic, but as a conflict between the ethical principle of autonomy and

health, as well as between the values of the patient and the values of the provider. Other studies have examined dialectal tensions—opposing needs that appear mutually exclusive but must be met simultaneously—that are created from patients and HCPs contrasting needs for autonomy and connectedness (Jameson, 2004). For instance, Brown and Levinson's politeness theory (1987) has been used to demonstrate how physicians, nurses, and patients are able to navigate through the autonomy-connection dialectic and create stronger collaborations (Jameson, 2004). The dialectal tension created between the opposing needs of ethical principles and the promotion of medication adherence, have similarly been explored within the context of nurse-patient interpersonal communication (Hess, 1996).

The remainder of this section will outline how the influence of the political/legal context factors, which were manifested as compliance regulations, created ethical tensions for clinical educators and challenged the way they coached and counseled patients to behavior change. The practical implications of this relationship between ethics and educator-patient interpersonal communication are large and significant to the industry and clinical educator programs. As such, many of those ramifications will be addressed at the end of this section and again at the conclusion of the chapter in the section on future studies. However, understanding the practical implications requires some analysis of this relationship from a theoretical perspective as well. As noted above, Street's (2003) ecological model provides some perspective regarding the association between medical ethics and the HCP-patient communication dynamic. Scholars have used other interpersonal communication frameworks though to further conceptualize this relationship, some of which will be explored below.

Ethical principles have long been viewed as a guiding force in patient education because of the educator's unique ability to influence an individual's learning, decision making, and consequent behaviors regarding their health (Clarke, 1993). Additionally, these principles are engrained as hallmarks of the nursing profession starting with nurse training programs (Tuckett, 2000). An ethical nurse is viewed as a moral agent who understands that being virtuous is not just expressed through her beliefs about how she should act, but also in her beliefs about how she should be. In other words, an ethical nurse is a state of character or orientation that serves to guide decisions that are right and good (Tuckett, 2000). Hence, it is not surprising that the clinical educators in this study, most of whom were nurses, placed such high value in honoring ethical principles such as autonomy, beneficence, and non-malfeasance. Though educators did not utilize those specific terms during interviews, the verbiage and descriptions they provided embraced their spirit.

For instance, the necessity for respecting and nurturing patients' autonomy was a prominent construct articulated throughout the interviews. One educator talked about the concept using the term "control," as in "You have to let people know they have some modicum of control over what's happening to them" while others referred to it using gerunds of "empower". Scholars support the synonymous interpretation of autonomy and empowerment that exists within the realm of patient education. Some studies have even suggested the two words can be used interchangeably since "the action for autonomy lies in its power base" (Clarke, 1993, p. 535). Reach (2013) believed that patient education in chronic care is contingent on empowerment, or catalyzed patient autonomy, particularly in the way that it helps patients account for their own and their HCP's concerns and

desires. Additionally, he felt patient education provides the vehicle by which patients can knowledgably choose between their own and their HCP's preferences. He noted, "Patient education is the empowering process that in chronic care not only provides information to the patients but also leads them to an interpretation of their own preferences and a deliberation between their, and the HCP's, preferences" (p. 20).

Many educators had beliefs about promoting autonomy, or empowerment, that would be reflective of Emanuel and Emanuel's (1992) interpretive model of physician-patient relationship. For example, educators' intense support of the ideal of patient-centricity would align to the concept of the interpretive model as they felt responsible for helping patients recognize and leverage their role as "the center of the healthcare team." For these educators, patient autonomy meant nurturing a patient's self-agency. Such an interpretation is reinforced by studies that have examined the concept of a patient-centric communication style as a type of predispositional influence. Those studies demonstrated that a patient-centric approach leads to better patient participation in a healthcare engagement (Cegala, 2011; Street et al., 2005).

Hence, educators in this study believed they had a unique moral imperative to their role. Though they were not part of a patient's primary healthcare team, they believed they were still responsible for helping patients assert their autonomy to that team while also teaching patients how to better communicate with their HCPs. Scholars such as Clarke (1993) would support such an interpretation. She posited that part of the autonomy-boosting role of the health educator is assisting patients in the development of *their own* decision-making and assertive skills required for self-development. Additionally, ecological perspective studies have shown that patients who receive

communication skills education and support are more likely to increase their level of participation in medical encounters with physicians (e.g. Cegala, 2011). Thus, by teaching patients how to better communicate with their doctors, educators saw themselves as resources that were helping patients meet broader health goals. Additionally, as Street et al. (2012) asserted, "identifying, clarifying and taking into account a patient's preferences for care is good clinical practice because it honors ethical principles of respect and autonomy" (p. 173).

Educators were also experienced in understanding and navigating the ethical antinomy that frequently presents itself when the principle of autonomy conflicts with other principles, such as beneficence. Some scholars understand this to be an ethical paradox; the desire to do good for the patient is at odds with the desire to ensure autonomy (Reach, 2013; Tuckett, 2000). In such cases, the ethical nurse recognizes that patient autonomy takes precedent. As Clarke (1993) explained, respect for autonomy is inclusive of the right of a patient to not comply with given instructions, or as one educator surmised, "Whatever they decide, I'm good with it. It's their life, it's their diabetes." Such a statement could easily be construed as representative of Emanuel and Emanuel's (1992) informative model or Rotor and Hall's (1992) consumerism model, both of which assert that the patient's values are clearly defined and articulated, and therefore, there is no need or place for the HCP's values. In these instances, patient autonomy dominates the interpersonal relationship. While some educators may have supported an informative model belief, the data suggested such attitudes were in the minority.

As the literature also points out, patient and HCP preference for these differing communication styles—informative, interpretative, deliberative—are rarely static and often change as patients progress through varying phases of the disease journey (Street et al., 2012). Therefore, regardless as to whether educators' and patients' communication actions and behaviors were indicative of the informative model or the interpretive model, educators still believed that a patient's right for autonomy in decision making was sacrosanct. Yet, such sanctity did not always absolve educators of feelings of moral ambiguity as evident by anecdotes in which they felt obligated to place autonomy over beneficence. As one educator had stated after a patient decided to continue taking a medication despite the educator's warning that doing so was unadvised as it was contraindicated to her other therapies, "It made me feel really uncomfortable, but I had to respect her decision."

Like autonomy, the ethical principles of beneficence and non-malfeasance functioned as a balance for the formidable influence of political/legal context factors that manifested themselves as compliance regulations. These two principles are understood to be harmonious constructs, often referred to as the principles of goodness and rightness; beneficence is defined as engaging in an act in order to benefit another, while non-malfeasance is defined as refraining from acting in a way that could inflict harm (Tuckett, 2000). For example, one educator's embracing of the Buddhist concept of loving kindness— "Going in where the patient is and being able to truly have their interest at heart"—signified how beneficence was a philosophical framework for how she, and many other educators, viewed the educator-patient relationship. Further, it engendered ethics scholars' belief that the dynamic of the nurse-patient relationship functions in such

a way to nurture the type of beneficence that could not exist outside of that relationship (Tuckett, 2000).

Within patient education, beneficence is safeguarded when the patient is fully informed and understands treatment information and its implications (Clarke, 1993). Educators recognized that, while the industry's frequent inflexibility toward adapting a presentation to a patient's specific learning needs was problematic, such compliance factors served to facilitate beneficence. Euphemisms such as "not sugar-coating things" and "giving them the good, the bad, and the ugly" further illustrated that educators conceptualized fair-balance presentation as an action of beneficence.

The findings also showed that, on occasion, the clinical educators' commitment to non-malfeasance was tested when it conflicted with perceived beneficence. While Tuckett (2000) noted that, when faced with a situation in which non-maleficence and beneficence come into conflict, non-maleficence should guide the decision, educators still struggled to resolved such dilemmas. One educator's moral deliberation regarding a perceived inverted risk/benefit ratio for patients prescribed a drug on which she provided education embodied that moral conflict. Other educators had noted that their commitment to non-malfeasance was tested when there was a conflicting sense of duty to a patients' HCPs and the perceived necessity to not contradict those HCPs. Such conflicts exemplified how the influence of political/legal context factors forced educators into ethical situations in which they had to choose between competing loyalties. The next section explores the interpretations of the three types of dual loyalty described in Chapter 4 and their relationship to the role of the clinical educator and the industry that employs them.

Interpretation of dual loyalty dilemmas. An ethical dilemma is defined as "a situation of a moral nature that requires a choice between two or more unsatisfactory or unacceptable options" (Gallagher, 1999). Additionally, the literature also uses varying terms to describe the divided sense of loyalty an individual faces when having to address the needs of two opposing entities. This includes dual loyalties (Beentjes et al., 2016; Gágyor et al., 2018; La Puma & Schiedermayer, 1989) conflicting loyalties (Lagerwey, 2010; Russell, 2012; Trandel-Korenchuk & Trandel-Korenchuk, 1982), and divided loyalties (Tabak, 1994; Weingarten et al., 2010). Navigating dual loyalty situations was likely not a new challenge for clinical educators as studies have shown nurses often face ethical quandaries when working in the field (Beentjes et al., 2016; Gágyor et al., 2018; Russell, 2012). Still, as evident from their anecdotes, educators' frequent experiences of moral distress regarding these conflicts are supportive of studies that assert such dilemmas can impede autonomous nursing practice and patient advocacy (Russell, 2012).

When sharing stories and beliefs of ethical dilemmas, educators spoke most frequently of the conflicts that arose between their patients and the industry that employed them. Common educator criticisms included a perception that companies were more concerned with program volume than program quality as well as the concern regarding the industry's inflexible attitude toward adapting programs to specific patient learning needs. In both instances, educators felt the industry's actions were shortsighted and contradictory to their programs' goals. However, educators also felt somewhat powerless to do anything about it, as evident by one educator who rhetorically asked, "Do I just stand there like a puppet and recite what the regulations tell me to say and walk away?" Situations such as this are not uncommon for nurses as they have a historical

precedent in the clinical setting. Both Thompson (1982) and Trandel-Korenchuk and Trandel-Korenchuk, (1982) asserted that nurses have frequently been unsupported or even thwarted in their ability to practice their profession by the very institutions responsible for patient care. Thompson placed blame for this disparity on the way the healthcare industry, at that time, had embraced a utilitarianism philosophy summarized by the phrase "the greatest good for the greatest number." As she pointed out, this can lead to ethical dilemmas for nurses whose principle concern is often with each individual patient currently under their charge. Not surprisingly, many of the clinical educators had concerns about the industry's perception of patients as a commodity, a belief that seemed to support Thompson's views.

Clinical educators in this study also found themselves occasionally at odds with the healthcare providers whose patients they educated. Some educators shared anecdotes of being caught as a mediator between a patient and their HCP or in situations in which they needed to, begrudgingly, defend a physician's actions or attitudes out of sense of professional courtesy. As Russell (2012) noted, the expectation of "nurses as mediators" between patients and physicians or patients and their families was common in the clinical setting. Therefore, such situations arising in the pharmaceutical clinical educator role is not surprising. Additionally, Thompson (1982) explained how, within the clinical setting, nurses typically feel obliged to support the physician, given his or her role as captain of the healthcare team, even if they feel a sense of sympathy or loyalty to the patients under their care.

As educators frequently educated patients in the presence of family members, they often encountered situations in which the expectations of the two diverged. Russell

(2012) explained that these conflicts can be tricky, especially when a nurse plays a part in an end-of-life situation or when a patient is unable to speak for themselves. All four of the educators who served on the network for patients with a terminal neurodegenerative condition spoke of the relationships they developed with families throughout the course of that year-long program and the challenges it posed. One educator's example of her need to mediate a discussion between a patient and her sister regarding the use of a feeding tube during the latter progression of the disease was one such example. That situation was illustrative of studies that found nurses were often conflicted between their duty to preserve a patient's autonomy and trust while simultaneously respecting the family member's need to properly care for the patient once the severity of the disease progressed to the point the patient could no longer self-manage (Beentjes et al., 2016).

These dilemmas are illustrative of Street's (2003) contention that the manner in which interpersonal communication happens between a patient and HCP is not simply the outcome of a single ecological context or an individual factor. Factors within the political/legal context—such as staying on-label, fair-balance presentation, and AE reporting—certainly presented educators with communication challenges to which there were no precedents to draw upon from their prior field clinician roles. Hence, for many of the dual loyalty dilemmas they faced, they could not reflect upon how they handled such an experience when working in a hospital or doctor's office. However, as noted earlier, Street's model is unique among other ecological perspective frameworks in that it narrows its focus to the engagements between patients and HCPs within the context of the medical encounter. As such, Street emphasizes the role of predispositional and cognitive/affective factors within the interpersonal context as having a greater weight of

influence in that communication dynamic. Because of this, educators struggled when the industry-centric value of "compliant behaviors are ethical behaviors" conflicted with the patient-centric values of autonomy and empowerment. They were challenged when emotionally driven factors, such as fear of legal repercussions or a necessity for allegiance to their fellow healthcare providers, forced them to consider alternatives to the messages they truly wanted to deliver to patients. Lastly, they grappled with whether they could compromise their preference for an interpretive communication style for employers who viewed their role as primarily a technical advisor or information conduit.

Implications of themes 1 and 2. Educators' commitment to ethical principles and their challenges for overcoming ethical dilemmas have implications for the industry and the policies that regulate them. Pharmaceutical companies need to recognize that for many of their clinical educators, including their most valued, experienced, and respected ones, the question of whether to be compliant is not a legal or policy matter. It is a moral and ethical issue. Despite liability concerns, policy directives, and compliance training programs, there will be educators who will engage in purposeful non-compliant behaviors, regardless of consequences, because they believe them to be the more ethical options and the ones necessary to avoid a breach of trust. One educator made such a belief entirely clear when she referred to an expectation to teach what she believed to be an unsterile self-injection technique by declaring "That's nuts! You know what? Fine me! Do whatever, fire me!" While this pronouncement may have bordered on the hyperbolic, it demonstrated in no uncertain terms that her commitment to the principle of non-malfeasance superseded any compliance obligation expected by her employer.

Interestingly, educators' passionate defiance of compliance protocols and their ongoing challenges in resolving ethical dilemmas presents a unique quandary for the pharmaceutical companies who hire them. If the industry wants to continue to benefit from the hiring of nurses and other highly trusted healthcare professionals for their clinical educator roles, they need to accept the ethical dilemmas those educators will continue to face given the current regulatory environment in which educators navigate. The companies' only other option is to hire non-clinicians, who, given the overly structured and scripted nature of some programs, could still deliver much of the content. Additionally, non-clinicians might be less likely to struggle with conflicts of professional ethics and therefore also be less likely to engage in purposeful non-compliant behavior that result from those conflicts. Unfortunately, though, non-clinicians lack the imbued trustworthiness associated with the nursing credentials that educators, and the industry, believe are necessary for most effectively coaching to appropriate disease self-management skills.

However, as the industry continues to embrace the use of credentialed clinicians for program delivery, it will need to do more than simply recognize and accept the moral tensions that exist in the clinical educator role if they wish to curtail the non-compliant behaviors that result from these tensions. To begin, pharmaceutical and patient services companies should address the moral and ethical stresses that permeate the clinical educator role starting with training and onboarding programs that acknowledge their existence and present strategies for addressing them.

As an insider to this industry, my experience has been that such trainings are largely absent in the industry. During my six years working as an instructional designer

and trainer for clinical educator services, I can state that, as far as VMS training programs, topics related to the moral implications and potential ethical conflicts that may arise as part of the clinical educator experience did not exist. In fact, when educators did receive structured information about ethical practices in the pharmaceutical industry, it was often only part of a mandatory training required by a Corporate Integrity Agreement (CIA) imposed on the pharmaceutical client by the U.S. Department of Health & Human Services' Office of Inspector General. A CIA is a punitive measure levied against pharmaceutical companies or other healthcare organizations who violate federal healthcare laws (U.S. Office of Inspector General, 2015). In addition to potential fines, corrective actions, and other scrutiny measures, most CIAs typically mandate that company employees and their agents receive training related to drug marketing and promotion annually for five years (U.S. Office of Inspector General, 2015). During my time at VMS, three separate pharmaceutical clients were under CIAs. As such, most VMS employees, including all educators for those client brands, were required to complete the computer-based CIA training. These training modules, as well as other VMS compliance training programs that were required of clinical educators, framed the ethics message within the principle of "compliant behaviors are ethical behaviors". Rarely, if ever, were contradictory ethical expectations inherent to the clinical educator role addressed in any VMS training program or policy documents to which I was privy. No VMS formalized training program during my tenure acknowledged that educators may experience moral dilemmas in which the ethical expectations of their employer conflicted with the ethical expectations of their profession.

While I can only speak definitively of the company for which I worked, I would postulate that such trainings are absent in most other companies that provide patient support services for pharmaceuticals. The reason for this belief is based on multiple rationales. First, any training program that addressed topics of ethical conflicts resulting from compliant behaviors could be perceived to contradict the industry's generally accepted principle that "compliant behaviors are ethical behaviors". In fact, patient services companies like VMS may be hesitant to even propose such trainings to their pharmaceutical clients. Doing so may be misinterpreted by the client as an indication that the patient services company hired poorly trained or sub-standard educators. Additionally, approval of such training programs by the client's MLR team could prove to be difficult, particularly if a client is under a CIA. Regarding the second rationale, all but two educators had prior experiences as a clinical educator working directly for a pharmaceutical company or for a VMS competitor. At no point during the interviews did any of these educators disclose having received such training in a prior position.

Lastly, companies will need to do more than develop strategies and training protocols that address those professional and ethical orientations. This should include working with regulators to create the type of policies that address those situations that force educators into ethical deliberations and potential breaches of trust. Regulators and the industry will need to look closely at the way they embrace and promote the philosophical orientation of "compliant behaviors are ethical behaviors." This maxim functions primarily as a legal endorsement for compliant actions designed to protect the populace from dubious promotional tactics such as white coat marketing, kickback schemes, and off-label product promotion. However, it fails to truly account for

expectations of autonomy, beneficence, and non-malfeasance, for which we also hold clinical educators responsible.

Conclusions and Implications of Theme 3

Theme 3 states, "A sixth context, the disease and treatment context, not previously identified in the ecological model literature, emerged from the interviews as having significant influence in the conversation dynamics between the educator and patient."

Conclusions of theme 3. Every educator discussed factors that influenced the communication dynamic with patients that were supportive of the ecological model (Street, 2003). Chapter 4 focused on educators' interpretation of the compliance and regulatory factors that manifested themselves as part of the political/legal context. However, educators described factors that aligned to Street's (2003) other contexts—cultural, media, and organizational—throughout the data. Additionally, they had provided insights that were supportive of the everyday talk interpersonal context described by Head and Bute (2017). Together, these factors are demonstrative of the core paradigm of ecological perspectives, which is the belief that behaviors and communication exchanges cannot be separated from the environmental and policy contexts in which they occur (Sallis et al., 2008). Street (2003) noted that within his model, these influencing factors happen simultaneously at multiple levels to include interpersonal, intrapersonal, organizational, community, and public policy.

This theoretically based explanation of Street's ecological model served to inform the rationale for a proposed modification to that model. However, as noted in Chapter 4, there were ecological factors that could not be accounted for by those contexts already

identified in the literature. Hence, this facilitated the need for an additional context—the disease and treatment ecological context—which is the thrust of this section. The argument for this new context is further catalyzed by the unique nature of my researcher role in this project and the way that role precipitated the interpretation of the interview data.

As discussed in Chapter 3 Methods, my role as a VMS employee and the experiences I acquired there as a program designer and trainer, provided me with a unique perspective toward this study and the way I interpreted the data. In addition to creating the program curricula, instructional guides, call scripts, and resource materials used by the brand networks, my VMS responsibilities also included a heavy focus on insights research related to a range of different disease types, their associated patient journeys, and the role of HCPs in helping patients navigate those journeys. Much of this research included collecting and reviewing qualitative studies published in the medical and social sciences academic literature. Other referenced sources included data garnered from patient profile dossiers written by clients' market research firms, as well as information gleaned from websites and resources published by patient advocacy groups, government health agencies, and HCP professional organizations. I synthesized this collected information into summary reports that I later used in developing program instructional methods and assessment measures. Additionally, this information was also utilized by VMS' business development personnel as a resource for creating customized sales pitches and business proposals.

These experiences provided me with a generalized knowledge of the physical, emotional, and social experiences of patients afflicted with various diseases and the way

those journeys influenced the interpersonal engagements patients had with their HCPs. More so, these experiences helped nurture a robust understanding of the complex interplay of ecological factors illustrative of Street's (2003) model. Finally, the training approaches I would use when onboarding educators to a program network often included lively discussions during which educators would disclose personal and professional experiences of patients' disease journeys. Thus, those conversations further affirmed and reinforced many of the beliefs and attitudes that I developed about the nature of disease and its impact on patients and HCPs. Such awareness would prove useful as I immersed myself in the data for this study.

During the data analysis process, I noticed insights and stories that, though they were clearly indicative of ecological phenomena that were influencing the educator-patient communication dynamic, did not seem to fit within the definition for any of the four socio-political context factors identified by Street (2003). Additionally, they were not supportive of factors associated with the everyday interpersonal context presented by Head and Bute (2017). For instance, some educators claimed that patients' perceptions of a product's lack of efficacy could directly impede their willingness to engage in on-going educational conversations. However, none of the ecological contexts defined in the literature would seem to account for the influence of treatment side effects, which include therapeutic failures, on the communication exchanges between the clinical educator and the patient. Similarly, multiple educators shared anecdotes of how they would spontaneously adjust their interaction approach to account for patients who showed up to a training and disclosed a comorbid condition. Yet, the influence of disease comorbidities would not fit within the definition of any of the existing ecological contexts. Thirdly,

educators who taught patients to self-inject often spoke of the need to adapt their communication approaches to account for the varying complexities of different injection devices. Like the prior examples, treatment administration modalities were not factors that would fit within any of the aforementioned ecological contexts. Together, these, and the other examples noted in Chapter 4 Findings, present a gap in Street's original ecological model of communication in medical encounters that is also not accounted for by additions to that model, such as the one suggested by Head and Bute. Additionally, these examples do not function as predispositional influences as they are not representative of communication styles or individual self-concepts. They also are not representative of cognitive-affective influences as they are not related to strategic, attributional, or relational considerations.

The remainder of this section examines this group of factors that emerged from the data and share a commonality of influence related to the presence of disease and how it is treated. For this study, it has been titled the disease and treatment context. The Chapter 4 Findings discussed different factors that comprise it. One such factor was *disease side effects*. Educators shared multiple examples of how the symptoms or indicators of a disease influenced the way they communicated with patients. One example was the challenges that arose when patients stricken with a progressive and terminal neurodegenerative disease lost their verbal functions. Educators also highlighted how the asymptomatic nature of diseases like osteoporosis or the early stages of diabetes, posed communication challenges; patients seemed less likely to be motivated to accept treatment for a condition for which there were no perceivable symptoms. A patient's prior or current experiences with *treatment side effects* also posed interpersonal

issues. Educators shared multiple examples of how they acted as adherence barriers. Additionally, a few educators pointed out that discussions of a medication's potential side effects required a different educational approach when the patient was pregnant or planning on becoming pregnant. The presence of *disease-related comorbidities* or *disabilities* functioned as ecological factors within this context. Educators shared various examples of how both physical comorbid conditions, such as hypertension or stroke damage, as well as mental health comorbidities, such as depression, would often require them to adapt their style of engagement or educational tactics. Similarly, educators explained how they would frequently need to spontaneously adjust their teaching strategies for patients with disabilities, such as vision problems or dexterity issues, that were often unknown to them prior to the start of a program. *Treatment administration modalities* served as another factor that influenced communication behaviors between educators and patients. Many educators focused on how the real or perceived complexity of administration devices such as syringes, autoinjectors, and infusion pumps required them to utilize a different instructional and conversational approach than if they were educating a patient on an oral medication.

The remaining disease and treatment context factor that was explored in Chapter 4 was *disease type*. Educators provided robust data regarding this factor and how it influenced their role and the way they engaged with patients. The Chapter 2 Literature Review provided examples of studies that have used Street's (2003) model for interpreting ecological factors *within* specific diseases, particularly chronic conditions such as diabetes, asthma, HIV, dementia, cardiovascular disease, and chronic pain (Fisher et al., 2005; Hruschak & Cochran, 2017; McKenzie et al., 2012; Mudd-Martin et al.,

2014; Rose & Garwick, 2003; Tan et al., 2014). Yet, the data from this study suggests that the *type* of disease was itself an influencing factor in the way educators choose to engage patients in conversations and education. Insights, beliefs, and anecdotes provided by educators demonstrated that they engaged in different communication approaches when speaking with a patient afflicted with a rare disease with few treatment options compared to those diagnosed with a common condition, such as diabetes or psoriasis, to which there are many medications. Phrases such as "they need more high-touch" and "there's a lot of therapeutic listening that goes in with those patients" served as exemplars of the communication challenges that distinguished rare disease patients from their common disease counterparts. Similarly, educators broached discussions with a patient experiencing a terminal neurodegenerative disease differently than the way they would approach a manageable chronic condition such as osteoporosis. As one educator had suggested about the difference with her terminal patients over her chronic disease patients, "The conversation becomes deeper."

Of course, none of these disease and treatment context factors operated in isolation. As ecological scholars point out, there is not just one single ecological factor that determines the full scope of influence between a patient and an HCP in the medical encounter. Rather, multiple ecological and interpersonal factors function simultaneously at multiple levels within communication engagements (Street, 2003; Street et al., 2005). Such interplay became evident when interpreting how disease and treatment context factors functioned within interpersonal influences. For instance, as educators engaged themselves in discussions or shared anecdotes of patient's disease journeys, they would often do so in a way that did not divorce the emotional experience of the disease from its

physical or technical aspects. In fact, at times it seemed as if the emotional journey was a synonymous or parallel experience of the disease journey. Street (2003) accounts for the role of emotions in the ecological model by explaining that they are a cognitive-affective influence that function as a mediator within interpersonal communication. In this study, patient emotions such as fear, anxiety, denial, and even shame frequently operated in conjunction with disease and treatment context factors.

For instance, educators who worked with osteoporosis patients described situations that exemplified the interaction of the emotion of denial with the context factor of disease side effects. They expressed how the asymptomatic nature of osteoporosis, when coupled with an inability to accept the disease and its relationship to the aging process, created a need for a communication approach that focuses on acceptance. One osteoporosis educator's statement had captured this thusly, "It's a silent disease. They don't believe they have it. And they don't want to start the treatment because that's admitting you're getting old because osteoporosis is seen as an old lady disease. I think it hinders their acceptance."

Implications of theme 3. Just as the addition of the everyday interpersonal context suggested by Head and Bute (2017) did not fundamentally change the core framework of Street's (2003) ecological model, neither would adding a disease and treatment context. In fact, as Head and Bute pointed out, an extension to the model not only provides a venue for new areas for research, it allows researchers to better interpret their findings within the framework of the larger model.

The participants for this study were pharmaceutical-sponsored clinical educators, and as such, the disease and treatment context is highly relevant to their role and

responsibilities. Moreover, it is the types of therapies for which these educators provide services that makes this context so significant for them. All the educators interviewed for this study educated patients on biologics or other medications that required parenteral (i.e. non-digestive system route) administration. Such medications typically require a different learning curve for mastering the administration process than education for an oral therapy. However, these medications do not tend to distinguish themselves from their oral prescription counterparts regarding their level of risk for adverse events. In general, parenteral administration typically does not account for either an increase or decrease in the overall prevalence or severity of side effects compared to oral medications. These drugs do though tend to have worse adherence rates than those taken orally because of the financial, emotional, and psychosocial stresses associated with them that function as barriers to self-care (Brixner et al., 2019; Lorenzi et al., 2011). Hence, any HCP charged with managing patients prescribed these types of medications, or the scholars who study this phenomenon, should find that this context provides a means for interpreting and better understanding the relationship between a patient's disease journey and their parenteral therapies. Additionally, scholars can view the clinical educator experience as one more context that supports the relationship between clinician communication and adherence (Duggan & Thompson, 2011).

Still, medication administration modality is not the only mitigating factor for consideration of this context. The data clearly revealed that the type of disease—chronic, rare, or terminal—served as a highly influential force in the way educators interacted with patients. Hence, this context is not just pertinent for those HCPs who prescribe biologics or other parenteral medications. It is particularly relevant to those non-

specializing HCPs who treat or manage patients with a diversity of disease types. This would include those who work in primary care, internal medicine, gerontology, or pediatrics. For instance, a primary care physician will still have on-going interactions with a patient who also sees a rheumatologist and has been prescribed a biologic for rheumatoid arthritis. A pediatrician may still provide general healthcare services for a pre-adolescent who also sees an immunologist and is self-infusing a medication to treat the rare condition of primary immunodeficiency. Many general practitioners in rural areas are often the sole source of care and the primary provider of in-office infusion services for patients afflicted with the terminal neurodegenerative disease noted in this study. Such patients are often physically or financially unable to travel to far-off cities to have their specialty medication infused by a specialist. The interpersonal communication skills of the doctors and support clinicians in all these situations can benefit from a robust understanding of the nature of the disease context and its influence on patients' willingness to actively engage in their own care.

Conclusions and Implications of Theme 4

Theme 4 states, "Educators employed communication strategies to navigate within the political/legal and disease and treatment context ecological factors."

Conclusions of theme 4. As evident from the findings noted in Chapter 4, the impact of the political/legal context and the disease and treatment context was such that the factors within these contexts often functioned as barriers toward fruitful interpersonal engagements between educators and patients. Subsequently, those barriers had the power to manifest themselves as adherence and self-management failures. Educators spoke at length of their frustration with compliance regulations and the way they adversely

influenced their engagements with patients. They also shared insights about how treatment side effects, disease comorbidities, parenteral medication administration modalities, and other factors of the disease and treatment context created communication and instructional challenges that were often difficult to overcome. Still, the educators persisted in their role as they felt they had the knowledge, experience, and requisite skillset to help patients navigate through many of these barriers. The remainder of this section explores those skills, strategies, and tactics educators utilized to address the challenges raised in Themes 1, 2, and 3.

One facet of this study that I found enjoyable, and that worked toward my benefit, was that the individuals I interviewed were subject matter experts in the area of patient-provider interpersonal communication. All educators reflected on their robust personal experiences with interpersonal communication as foundational to their understanding of how to effectively engage patients. However, many of them also referenced specific university courses or formal post-graduate classes in patient-provider communication that were part of a credentialing or professional development program. Others referred to communication training sessions they received through workshops, certificate programs, or as part of an employer's onboarding process.

Not surprisingly, communication is recognized as a foundational skill for the nursing profession as evident from Standard 9 of the American Nurses Association's (ANA) Nursing Scope and Standards of Practice which states, "The registered nurse communicates effectively in all areas of practice" (American Nurses Association, 2015, p. 71). Three competencies within that standard are especially relevant to the focus of this study. These are: (1) the registered nurse incorporates appropriate alternative

strategies to communicate effectively with healthcare consumers who have visual, speech, language, or communication difficulties; (2) the registered nurse assesses communication ability, health literacy, resources, and preferences of healthcare consumers to inform the interprofessional team and others; and (3) the registered nurse uses communication styles and methods that demonstrate caring, respect, deep listening, authenticity, and trust (American Nurses Association, 2015, p. 71).

The educators' recognition of the value of communication as an essential skill was evident throughout the interviews and focus groups. Many of the educators spoke of the relationship between communication and clinical outcomes at a level indicative of advanced scholarship in the matter. They shared anecdotes and personal experiences that showed they not only internalized the ANA communication standard and its associated competencies, but understood their proper application in the field and in the industry.

Educators used multiple communication strategies to address the difficulties posed by the compliance factors of fair-balance presentation, staying on-label, and adverse event reporting that were inherent to the political/legal context. A few educators indicated that they felt the best strategies were the pragmatic ones. In other words, these educators believed the best course of action was simply to stick to the rules—i.e. strict adherence to program materials and guides, no deviation from call scripts, and direct and unqualified deferrals back to the HCP when off-label questions arose. Some of the educators who advocated this viewpoint may have done so because they had internalized the pharmaceutical principle of "compliant behaviors are ethical behaviors." Therefore, they placed the greatest value on industry-centric strategies because they believed doing so was necessary to maintain a sense of ethical centeredness. This rationale was

exemplified by educators' strategy for addressing fair-balance presentation, which they described with euphemisms such as "not sugar-coating it" or "giving them the good, the bad, and the ugly." As noted earlier, educators saw this approach as a moral imperative because it reinforced their commitment toward ensuring patient autonomy.

Of interesting note though is that educators who adopted a "stick to the rules" predispositional influence may have done so out of a belief that they were upholding their ethical principles. However, the industry-centric nature of that kind of presentation would most likely result in a communication style illustrative of the informative model (Emanuel & Emanuel, 1992), something few educators seemed to espouse. As evident from the interview responses though, the other likely reason why some of them were supportive of a stick to the rules approach was purely out of a need for self-preservation. Educators feared putting themselves at legal or disciplinary risk by engaging in any strategy that bordered on, or was perceived to border on, the non-compliant. As Street (2003) explained, emotional factors, such as fear, that make up the cognitive-affective context can greatly influence how an HCP engages with patients interpersonally. So, though educators who valued an absolute and pragmatic approach to program delivery may have believed they were doing so out of a moral obligation for ensuring autonomy, their true rationale may have originated from their own emotional orientation.

Regardless, most educators shared ideas and examples of tactics and strategies that, in their view, allowed them to effectively navigate through compliance-related limitations. They did this while keeping within "the letter of the law," or as one educator's euphemism of "almost compliant" would imply, at least the spirit of the law. In many ways, educators' efforts to employ solutions for overcoming compliance-driven

communication problems were emblematic of their commitment to both an interpretive model of interpersonal communication (Emanuel & Emanuel, 1992) as well as the ANA Communication Standard's (2015) competency of "The registered nurse incorporates appropriate alternative strategies to communicate effectively with healthcare consumers who have visual, speech, language, or communication difficulties" (p. 71). Educators recognized that it was their responsibility to uphold the spirit of this standard by finding solutions for compliance-related communication issues.

For instance, educators occasionally trained patients who may have been prescribed an off-label dosage of their medication or instructed by their physician to administer it in a different manner than outlined in the prescribing information. Educators shared examples of nonverbal gestures or linguistics tactics, such as voice inflections or key-word emphases, to help alleviate confusion that arose when a physician's instructions contradicted the materials they used during instruction. This was an important strategy since educators were not allowed to deviate from those materials but still needed patients to understand the importance of following their physician's recommendations.

Educators were also keenly aware of the risk to trust bonds that could arise when they were required to defer off-label questions back to patients' HCPs. This threat was why so many of them offered detailed strategies beyond just an unqualified statement of "You need to talk to your doctor about that." One simple yet effective tactic was to provide patients the rationale for why a question could not be addressed. Educators noted that patients were mostly accepting of that pronouncement if they were also made aware that there was a legal or policy reason for it. Additionally, educators would explain to

patients that, because they lacked access to full medical histories, any attempt to address an off-label question could be unsafe and unethical. Other educators chose to enlist a proactive approach to this strategy by informing patients at the start of the engagement of their limitations for addressing certain questions. Some educators believed trust bonds could be unaffected if they acknowledged the validity of a patient's question and then sought out the motivation for it.

Educators also employed tactics that actively engaged the patient in the solution. For instance, a few educators thought it was helpful to have patients write down questions that could not be addressed, so the patient could then share them with the physician during their next visit. Educators recognized that some patients have had bad experiences in which they did not receive a return call from their HCP office after leaving a message that included questions for the physician to address. In those instances, educators would often defer the patient to their company's medical information line that employed clinicians with the authority to address a broader range of topics. Lastly, educators understood that a segment of their population was intimidated by asking their physician questions. For those situations, educators explained that they would take on the role of an intermediary by offering to pose the question to the physician on the patient's behalf.

According to assertions offered by Street (2003), educators use of these different strategies would serve as evidence of their desire to embrace interpersonal communication in a way that upheld the spirit of the interpretive model (Emanuel & Emanuel, 1992). He claimed, "A provider who shows interest in what the patient is saying and solicits opinions or questions is in effect legitimizing the patient's

involvement as well as creating opportunities and expectations for the patient to elaborate on issues of concern" (p. 70). As discussed earlier, this notion of "legitimizing the patient's involvement" reinforces the responsibility educators felt for helping patients assert their autonomy to the formal healthcare team—a team to which they were not part. Educators who took on the role of an intermediary between the patient and their provider felt empowered to do so not just because of an ethical obligation. They took such action as it was driven by a predispositional influence that valued patient centricity as fundamental to interpersonal communication.

Educators handled other issues in ways that are emblematic of the ecological model. One challenge faced by educators when presented with an AE was how to simultaneously encourage the patient to share the information with their HCP while not inciting alarm. Interestingly, multiple educators suggested that the best way to handle the situation was to use the AE as a teachable moment to help patients understand concepts like comorbidities, the risk/benefit analysis their physician performs before prescribing a medication, and how some, but not all, side effects are captured as part of a drug's clinical trial process. As with off-label questions, some educators also served as intermediaries to physicians by assisting the patient in disclosing the AE. Telephonic educators also recognized the challenges posed by a reported AE, particularly if it was the type of side effect that required a visual inspection. Educators would often impress an urgency with patients to have such reactions immediately examined by their HCP, or if warranted, emergency services. Once again, these strategies demonstrated how educators engaged patients in a manner that nurtured their confidence, thus reinforcing

studies that asserted such actions can lead to greater levels of participation from patients in future healthcare exchanges (Cegala, 2011; Street, 2003; Street et al., 2005).

Lastly, when educators shared how they addressed disease and treatment factors that were functioning as communication and behavioral barriers, their answers were indicative of the ANA Communication Standard's (2015) competency of "The registered nurse uses communication styles and methods that demonstrate caring, respect, deep listening, authenticity, and trust" (p. 71). Of the three competencies noted, this one directly addresses the importance of communication style. Even more so, not only does it recognize the significance of style, it offers specific values that define an ideal version of it; the first four—caring, respect, deep listening, authenticity—often serving as mediators of the final one, trust. Hence, clinical educators who used communication strategies that were indicative of the values of this ANA Communication competency, would also be likely to support a philosophical orientation that aligned to the interpretive or deliberative models of interpersonal engagement.

For instance, some educators spoke about the ways they tried to find a type of "connectedness" with the patient, or a means for the patient to feel like they were in a partnership with the educator. For some, that meant using inclusive pronouns such as "we" or "us." Educators had also stressed the importance of recognizing the uniqueness of the disease experience for each patient as well as the importance of avoiding making assumptions about experiences with prior treatments. When addressing side effects and treatment administration barriers, educator sought to correct common misconceptions that were often related to topics such as insulin failure, device needle size, and injection pain.

Additionally, educators frequently embraced the use of administration demonstrations via practice devices or online videos.

Implications of theme 4. The strategies educators used acted as a counterbalance to the potential deleterious effects that were possible from the political/legal and disease and treatment context factors that functioned as communication and behavioral barriers. Educators acutely understood that these barriers possessed the capability to extinguish medication adherence and sabotage proper disease self-management behaviors. They also recognized that, unlike in their field clinician roles, there were more and different limitations in the way they could address those challenges.

Interestingly though, educators still drew from their knowledge and experiences as field clinicians to assist them in their efforts. During their interviews, educators were asked to identify patient communication best-practices they learned during their prior experiences working in the field that were important to their pharmaceutical educator role. Some of their responses included common-sense communication tactics such as making eye contact, being an active listener, making sure to account for body language presentations, and providing consistent and on-going verbal encouragement and support. They also stressed the importance of gathering a historical understanding of patients' experiences at the start of any engagement as well as the necessity for maintaining an on-going balanced assessment of both the patient's comprehension, as well as the communication dynamic. This included continuously reflecting on the type of linguistics they used and how they were delivering information. One educator referred to this as part of "the art of nursing" though such skills are also characteristic of the ANA Communication Standard's (2015) competency of, "The registered nurse assesses

communication ability, health literacy, resources, and preferences of healthcare consumers to inform the interprofessional team and others" (p. 71).

The main implication that can be synthesized from such evidence is that the role of the pharmaceutical clinical educator is best served by clinicians who have had broad and varied experiences providing patient education in the field. Currently, most pharmaceutical companies who provide patient education services, along with the patient support services companies like VMS who are contracted to run them, have followed such a model by utilizing highly skilled field-experienced clinicians. However, like most industries, pharmaceutical companies are always seeking to control costs. Using seasoned and credentialed clinicians is far less affordable than hiring non-clinicians. Given how some educator programs are highly scripted and provide little room for customization, a cost-controlling pharmaceutical executive might lean toward the non-clinician option if they perceive a lack of necessity for clinical expertise. However, as apparent from the findings of this study, the value and skills field-experienced credentialed clinicians bring to their role is why educators can effectively overcome the shortcomings associated with scripted programs. That same experience is also why they can successfully navigate through many of the other barriers posed by political/legal and disease and treatment context factors.

Conclusions and Implications of Theme 5

Theme 5 states, "Educators believed they needed to establish and maintain trust throughout the engagement process for them to successfully solicit meaningful patient disclosures."

Conclusions of theme 5. A core commonality that runs throughout the findings of Chapters 4 and 5 is the notion of trust. The concept is a core construct within the context of Street's (2003) ecological model of communication in medical encounters as well as in Petronio's (2002) communication privacy management (CPM) theory. In Chapter 4, educators conceptualized trust in relation to each of the three compliance factors that served as predominant influences on the educator-patient relationship. Educators expressed the importance of not sugarcoating information as part of their responsibility for fair-balance presentation, lest they lose trust. They recognized the necessity of utilizing nuanced communication strategies to avoid the erosion of trust when required to defer a patient's off-label question. They also leveraged established trust by ensuring a reported AE did not unduly alarm a patient while simultaneously impressing upon that patient the importance of informing his or her HCP.

Trust is foundational to the framework of CPM theory (Petronio, 2002). Studies that have examine the application of CPM theory within the context of healthcare have asserted its value for understanding the way patients and HCPs manage private information (Hammonds & Ribarsky, 2018; Petronio et al., 1996; Petronio & Sargent, 2011). Just as educators understood the importance of strong trust-bonds for navigating compliance barriers, they also recognized its necessity for helping patients feel comfortable and confident when sharing private information.

An interesting notion that had propagated throughout some of the interviews was that educators, by nature of their role and status as nurses, benefited from a high level of imbued trust that was not afforded to other professions, including other professionals in healthcare. Though some educators disagreed with such a belief stating that trust could

only be earned, those that did support the concept of assumed trust based the idea on a popular annual opinion poll. Nurses have been ranked as *the* most honest and most ethical profession every year but one between 2000 and 2020 by Gallup's annual public opinion poll on the topic (Brenan, 2018; Reinhart, 2020). Popular consumer media and nursing's professional organizations have often reframed the "most honest and ethical" message to be synonymous with "most trusted" (McCarthy, 2019; Stone, 2019). Of course, whether the small subset of the general populace who participate in pharmaceutical-sponsored clinical educator programs hold similar beliefs about the trustworthiness of their educator is beyond the scope of this study. Still, the perception by many of the educators was that they enter their educational and coaching engagements with a beneficial amount of trust already instilled in them by their patients. Accordingly, they believe that predisposed trust worked toward their advantage when soliciting information from patients.

Educators' belief that patients automatically instilled trust in them, and therefore willingly disclosed information, was interpreted within the context of the opinion polls that characterized the profession as honest and ethical. However, the CPM literature would suggest other interpretations for educators' perceptions of assumed trust. One relevant explanation is Petronio's (2002) concept of "trust credit points." These are figurative increments of trust given to an information recipient from the discloser that can increase or decrease based on how the recipient manages the disclosed information. If the recipient breaks negotiated privacy rules, he or she loses points and must engage in actions or a renegotiation of rules in order to restore them. In the context of this study, educators perceived patients as providing them with many points at the start of their

engagements. If educators maintain their expectations and obligations for patient privacy, they held on to those points.

Another possible explanation discussed in the CPM literature is that patients' willingness to automatically instill trust was the result of the patients' functional need to receive healthcare (Petronio et al., 2012). In other words, patients trusted educators and were willing to disclose information to them because they knew that, in exchange, the educators would assist them with their healthcare needs. This is the main premise of the stakeholder confidant role noted in the CPM literature (Petronio & Sargent, 2011) and described in Chapter 5. It is discussed in greater detail later in this chapter.

Still, there was a sense among some educators that trust was not inherent and therefore they still needed to earn it—or at least earn more trust than what was automatically assumed. Additionally, once trust was received, it had to be maintained in order to facilitate an on-going exchange of information. When establishing trust, educators spoke of strategies that leveraged their empathetic nature, such as assuring patients at the beginning of the program that they understood their challenges and had their best interests at heart. Another shared strategy educators used for making a personal connection was to start engagements with a disclosure of personal information about themselves. This tactic could be considered a characteristic of Petronio's (2002) concept of the deliberate confidant. That role is one in which a recipient, who has actively solicited private information from another for coaching or counseling purpose, may reciprocate by sharing their own personal information out of an obligation toward trust. This confidant role is also discussed in greater detail later in this chapter.

Educators described many different ideas and strategies for maintaining trust once it was established. For instance, some expressed that their ability to spend quality time engaging patients in discussions of their health helped to sustain trust, especially given that some patients' adverse attitudes about the amount of time their HCP affords them. One educator noted in Chapter 5 that she strengthens trust by sharing her frustration with patients regarding her inability to speak to off-label topics. She had stated, "They know I care, they know that I'm a little frustrated or unhappy…because we're sharing that experience together…that strengthens the bonds and rapport more so than it harms." This was an interesting insight that highlights the relationship that exists between Street's (2003) ecological model and CPM theory. It demonstrates that, for both disclosers and recipients, the ability to establish the sort of trust that can facilitate the sharing of private information does not occur in isolation of ecological and interpersonal influences.

Though the educators worked diligently to maintain trust, they also recognized that loss or erosion of trust was possible. Such loss could be precipitated by what Petronio (2002) referred to as boundary turbulence. This is when an unintended or purposeful breach of negotiated privacy rules by the recipient forces the discloser to change the thickness of boundary permeability and/or renegotiate the privacy rules. Educators sought to avoid boundary turbulence and loss of trust as they believed these could impede patients' comprehension and hinder achievement of disease self-management goals.

Implications of theme 5. Educators may have had varying beliefs about whether trust was imbued, earned, or situationally dependent. However, all seemed to coalesce around the idea that it was a value that needed to be constantly nurtured and maintained

throughout the tenure of their engagements with patients. Multiple educators had used the phrase "open and honest communication" to describe their preferred strategy for maintaining trust when soliciting and receiving private information. Others utilized similar terms such as "being upfront" or "being transparent." In fact, educators understood such transparency to be a requisite for ensuring patient autonomy, as noted in their reference to giving patients "the good, the bad, and the ugly," that was part of their obligation for fair-balance presentation. Yet, there is incongruity between their support for open and honest communication as a strategy for facilitating disclosures and the reality of compliance regulations that inhibit them from sharing "unapproved" information regarding diseases and/or treatments. So, while educators may *value* or strive for complete transparency and an open and honest approach for communication, their ability to deliver full, unfettered information, ideas, and opinions is an idealistic goal, but not a realistic one.

This realization has implications for educators' interpretation of trust as well as for how they set the tone of their engagements with patients. Educators should avoid the use of messaging or the setting of expectations that implies they will be *completely* open and forthcoming in their communication with patients. In reality, their ability to address all of the questions or information requested by patients is not possible. Hence, an educator who tells a patient they will always be "completely open and honest" stands a greater risk for damage to trust bonds when deferring an off-label question than the educator who set qualified expectations about their limitations for information sharing. As many educators had pointed out, any erosion of trust can severely impact patients'

willingness to disclose the type of health information they need to properly educate and counsel.

Conclusions and Implications of Theme 6

Theme 6 states, "Educators managed the information disclosed to them by patients using routinized rules based on core privacy rule decision criteria as well as changing rules based on catalyst privacy rule decision criteria."

Conclusions of theme 6. When educators were asked a general question during the interviews about the role of privacy in patient education, they answered from two different perspectives, their own and the patients'. Arguably, the best way to truly understand patients' interpretation of privacy is to gather that data directly from them, something that was outside the scope of this study. Still, the educators were able to ascertain a unique understanding of patients' conceptions of privacy based on the educators' observations and experiences engaging with them. As noted in the Chapter 5, educators did understand that their patients utilized privacy rule decision criteria to manage how they shared health information with family, friends, and others. However, educators did not use the CPM terminology associated with privacy rule decision criteria—i.e. boundary permeability, core decision criteria, catalyst decision criteria, routinized rules, and changing rules— to explain their views during interviews (Petronio, 2002; Petronio, 2013). Still, educators shared multiple stories and anecdotes that exemplify the spirit of privacy rule decision criteria and privacy rule decision making as interpreted from patients' perspectives.

For example, one exemplary anecdote noted in Chapter 5 demonstrated the process by which an educator was able to interpret the concept of *cultural values*—a

CPM criteria for privacy rules decision making—that was supportive of assertions found in the literature. Cultural applications of CPM have been the subject of many studies in the literature (Petronio, 2013), including those that have focused on the health experiences of the African American community (Dillon & Basu, 2019; Gaskins et al., 2012; Hovick et al., 2015). In the current study, an educator who was white had shared how, in her own personal experiences, family medical histories were known and willingly shared among immediate family members and other close relatives. However, she went on to assert that that was frequently not the case for many of the African American diabetes patients with whom she worked. She cited examples of spouses or adult children of parents not being aware of their family member's current treatments and disease management requirements, as it was not communicated between them. She had shared how those experiences led her to believe that that type of interfamilial communication dynamic was culturally related.

Studies from the literature would back up her hypothesis. Lin et al. (2018) found that, when compared to their white counterparts, African American diabetes patients were more likely to have uneven distribution of family medical history knowledge (i.e. one informant knowing and the other not knowing). The study also found that African American family dyads (i.e. husband/wife, parent/child) had fewer reciprocating health communication ties than white family dyads. Studies in the genetic counseling literature would support the educator's contention as well, although with the caveat that other social determinants *within* a race, such as education level and socioeconomic status, could scale the influence of interfamilial communication (Ashida et al., 2012; Thompson et al., 2013).

This was one example of how educators' interpretations of patient behaviors were representative of CPM's privacy rule decision principles, but it was not the only one. Educators explained that patients often used varying degrees of boundary permeability. They shared stories of patients exhibiting different tolerances for disease disclosures to families and others. Interestingly, the educators framed those interpretations within the context of professional ethics, maintaining that each patient had "the right" (i.e. autonomy) to determine privacy boundaries. Therefore, if a patient desired to not disclose a diagnosis or treatment to their spouse, the educator was obliged to respect that decision. Such predicaments parallel findings by Petronio and Sargent (2011) who had found that hospital nurses struggled with similar dilemmas that weighed privacy against standards of professional ethics.

Interestingly, while many educators cited examples in which respect for patient autonomy equated to limiting or constraining the sharing of personal health information, others had provided instances of a contrary phenomenon. A few educators cited examples of patients who, because they had experienced successes with disease management, were motivated to share their disease stories with newly diagnosed individuals that participated in the educators' group education classes. Such instances would exemplify the process by which motivational goals, a CPM catalyst criterion for privacy rule management, leads to changing rules (Petronio, 2002).

Like their patients, educators relied on privacy rule decision criteria to manage patients' private information. These criteria included the core criteria, which resulted in routinized rules, and catalyst criteria, which produced changing rules. Routinized rules are stable and promote routine privacy management behaviors. Conversely, changing

rules are flexible and result from triggered catalyst rule criteria based on situations, motivations, and emotions (Petronio, 2002; Petronio, 2013). Chapter 5 examined educators' privacy rule decision criteria, both core and catalyst, within three parameters: professional ethics, political/legal context factors, and insights educators gathered from their observations of the way patients' managed privacy.

Nurses' ethics as a factor for understanding privacy management decision has been examined in studies both within and outside the CPM framework. For instance, Kim, et al. (2017) noted that nurses *perception* of how well they managed patient privacy protection was higher than their actual management performance. They attributed this phenomenon to how nurses' strong desire for honoring patient autonomy created a false perception of actual practice. Suzuki, et al. (2015) found that, when making privacy decisions, nurses would place weighted value judgements on the patients' right to autonomy based on the nature of situation. If a situation was life-threatening, nurses' respect for patient autonomy would come secondary when deciding to whom to make disclosures. When interpreted within the framework of CPM theory, the ethical principles that guided educators' decisions regarding their compliant (or non-compliant) actions were the same ones that were also foundational to the routinized rules educators used when managing private information while working in the field. Many of the routinized rules from the clinical field followed educators to their pharmaceutical role as did the ethical principles on which they were built. When discussing patient privacy management, educators' responses were most reflective of the ethical principle of respect for autonomy. This was not surprising since many educators tended to give deference to this principle when it conflicted with others such as beneficence and non-malfeasance.

Petronio, et al. (2012) accounted for this deference noting that, from a CPM perspective of the HCP-patient relationship, "managing privacy means navigating between the need for autonomy and the need for connectedness" (p. 41). Educators strove for connectedness with their patients that was best accomplished through thin privacy boundaries that facilitated rich and unfettered disclosures. Yet, educators' reverence for patient autonomy also meant they respected the wishes of patients who chose thick privacy boundaries. Hence, much like their compliance-related dilemmas, educators' decisions related to privacy management also proved ethically challenging.

The ethical principles parameter that helped guide educators' privacy rule decisions originated from their prior experiences as field clinicians working in hospitals, clinics, and physician offices. The second parameter, political/legal context factors, commenced from those experiences as well and therefore exemplify an intersection of Street's (2003) ecological model and CPM theory (Petronio, 2002). When asked to interpret the nature of privacy in their pharmaceutical role, many educators referred to the influence of their years of experience working as field clinicians under various kinds of government and healthcare industry-imposed privacy regulations. One outcome of working under government policies in hospitals and physicians' offices was that educators developed routinized privacy rules that they uniformly applied to all patients.

When educators discussed privacy regulations, some referenced specific policies or legislation—most frequently HIPAA, the Health Insurance Portability and Accountability Act—while others spoke of them in a more generalized nature. This was not surprising as Petronio and Sargent (2011) pointed out that, along with a code of ethics, regulations and legislation such as HIPAA often serve to define nurses'

parameters of patient confidentiality. Those educators who did specifically mention HIPAA tended to be well-versed in its applications. This was most likely a result of how HIPAA is often interpreted by nurses as the hallmark legislation related to the protection of individuals' health information (Erickson & Millar, 2005). That understanding is predicated on the HIPAA Privacy Rule, the federal regulation that set the standards by which individually identifiable health information is electronically transmitted among stakeholder entities (U.S. Department of Health and Human Services, 2015). When employed by a hospital, clinic, or physician's office, a clinical educators' role would fall under the HIPAA designation of a "covered entity," meaning they are legally bound to the privacy obligations outlined in the HIPAA Privacy Rule. As an employee or contractor for a pharmaceutical company or patient support services company though, educators fall outside the official designation of covered entity. Instead they would be recognized as the HIPAA designation of a "business associate" of covered entities, as they receive identifiable health information from covered entities. In that regard, educators are still expected to abide by the HIPAA Privacy Rule (U.S. Department of Health and Human Services, 2009).

The concrete and unambiguous nature of federal privacy laws such as HIPAA functioned as core criteria for the routinized rules that educators applied across their career paths. Additionally, the ethical principles that guided their profession's moral compass were similarly unyielding and thereby also functioned as core criteria for routinized privacy rules (Petronio & Sargent, 2011). The third parameter though that provided a framework for privacy rule decision criteria was the insights educators garnered from their observations of how patients managed their private information with

others. In other words, educators would develop privacy rules for patient interactions based on what they observed about the way patients managed privacy rules with families, friends, acquaintances, and others. As such, this parameter tended to be more represented by catalyst criteria and changing rules.

The prior case of the educator who noticed differences in interfamilial communication with her African American patients serves as an exemplar of this phenomenon. According to this educator, because of cultural expectations inherent within that community, black patients were less likely than white patients to know or disclose family medical histories among close family members. That cultural expectation functioned as a core privacy decision criterion for patients who were part of that community. The educator later went on to explain that she eventually started adjusting her communication approach when working with African American patients and/or family members because of her observations. Her decision to adjust her privacy rule was provoked by the situational condition of the presence of family members when training African American patients. Thus, her actions are exemplary of CPM's assertion that situational conditions can function as catalyst criteria for privacy rule changes (Petronio & Durham, 2008; Petronio, 2013).

Educators shared other examples of situational conditions that were indicative of catalyst criteria that prompted privacy rules changes. For instance, telephonic educators explained that they would occasionally need to spontaneously adjust their conversational style and approach when they perceived that the patient they had on a call was in a physical setting that lacked privacy, such as a store or busy office. Additionally, educators explained that the privacy rules they established with patients were frequently

adjusted based on patients' attitudes or tolerances for using that communication modality for health engagement purposes. Patients who had little or no prior experience with telephonic education often displayed skepticism toward educators' intentions, especially during the first call. As Petronio (2002) points out, emotions, such as skepticism or distrust, can also function as catalyst criteria that force recipients of information to adjust their privacy management behaviors. Other emotions, such as the embarrassment related to disease stigma, similarly served as privacy management rule catalysts, particularly in the group education classes that some of the educators led. Educators shared how the presence of a range of emotions within each class, from acceptance to ambivalence to shame, could prove challenging when trying to manage privacy expectations of every member of the group. According to the educators, some patients found the offering and receipt of personal disclosures regarding disease journey experiences to be therapeutic while other patients preferred simply listening and avoided making any contributions to discussions.

Implications of theme 6. Many of the everyday decisions clinical educators make about patient privacy are driven by policies and structures outside of their control. These include federal government acts such as the HIPAA Privacy Rule as well as industry policies such as those rooted in liability protection purposes. For instance, one example mentioned in Chapter 4 is the expectation that educators should not keep handwritten notes regarding their patients. Such laws and regulations function as routinized rules that leave little room for wavering. However, much like the impact of compliance regulations on educators' ability to customize programs, these rules have ethical implications for privacy. As noted earlier in this chapter, educators are not trained

on navigating the relationship between their ethical orientations and the privacy rules that can impact their communication approaches and patterns with patients. A case in point is the educator who adjusted her privacy communication behavior for her African American patients. She did so because of her belief that cultural expectations, inherent to that community, influenced the way they disclosed family medical histories among family members. For her, adjusting her approach was an ethical choice grounded in her core decision criteria even though the situation itself (i.e. the presence of family members) functioned as a changing rule. She believed adapting her privacy management practice was ethically necessary to protect the patient's autonomy. However, that choice may have also violated her network's compliance regulations, which stipulated she should not make unapproved changes to her program delivery methods.

As noted previously, educators receive little training or guidance for resolving the tensions that are created when professional ethics conflict with practice expectations. Such conflicts, as they relate to patient privacy, is no exception. Educators receive formal training on the practical tenets of laws and regulations like HIPAA, but rarely on their moral or philosophical impact. This is something that should be addressed through structured training and professional development programs given the influence of professional ethics on the clinical educator role.

Conclusions and Implications of Theme 7

Theme 7 states, "Educators managed multiple types of confidant roles with patients including stakeholder, deliberate, and reluctant.

Conclusions of theme 7. CPM theory identifies multiple types of confidant roles for representing the nature of relationships between a discloser of information and the

recipient. Three of them were identified in Chapter 5 as relevant to this study—the stakeholder confidant, the deliberate confidant, and the reluctant confidant. The remainder of this section will examine how those roles were interpreted in relation to the Chapter 5 findings as well as the implications for the pharmaceutical clinical educator profession.

Interpretation of the stakeholder confidant role. Unlike the other types of confidant roles which have been interpreted across many different domains, the stakeholder confidant has been examined in the literature primarily as it relates to physicians and nurses in the healthcare context (Helft & Petronio, 2007; Petronio & Sargent, 2011). As the name implies, the stakeholder confidant status develops because the HCP functions as a stakeholder in the patient's care. However, the role as addressed here is more limited than what is described in other studies that have explored its meaning in the context of clinicians in the field. Still, key assertions from the literature are relevant to the experiences of educators in this study.

Petronio and Sargent (2011) noted that the privacy boundaries that are inherent to the stakeholder confidant roles are co-created by the nurse and patient for two reasons, "because of patients' emotional needs to disclose feelings about a medical state and to tell the nurse private medical information to receive health care" (p. 256). The latter reason noted in that statement was touched upon earlier as a potential rationale for why educators were automatically imbued with a high degree of trust from patients. Patients gave educators trust credit points because, in return, the educator would assist them in learning how to administer medication and manage their disease. Petronio (2002) used the term trust credit points to explain a predisposition of trust provided to a recipient of

information from the discloser. Hence, the stakeholder confidant role could be understood as a role that includes imbued trust. This interpretation was evident in one educator's comment, who said, "They know I'm a nurse, and I'm coming to teach them. And I've got their information from their doctor. So, he must trust me if he gave me their information. So, kind of opens up the communication." The educator's statement points to three factors that highlight characteristics of the stakeholder role: (a) a reference to her purpose of providing health services, (i.e. "I'm coming to teach them"), (b) her acknowledgement that her credentials as a nurse carry weight for receiving predisposed trust, and (c) her reference to the physician, another stakeholder confidant, and how his trust in her helps affirm a patient's willingness to accept her as a stakeholder as well.

Educators perceived themselves to be trusted by patients as stakeholder confidants. Educators also knew that patients saw them as a resource for accessing healthcare information—a criterion of the stakeholder confidant's role. In fact, as some educators were quick to point out, patients often turned to them for additional disease information and services that would typically be the purview of the physician or his/her office staff. A few educators had surmised that this phenomenon happened because educators were viewed as more accessible and were therefore, prioritized over a physician for questions or concerns.

The second reason, according to Petronio and Sargent (2011), why educators were able to co-create a stakeholder confidant role with patients was because there was an emotional need by patients to disclose feelings about their disease. Responses from educators as to *why* patients were so freely able to disclose information to them was because of the trust that was vested in the educators. Trust not only functioned as an

incentive for driving patients' disclosure of disease experience information, it also functioned as a vector by which patients could engage in emotional disclosures related to their journey. For instance, many of the osteoporosis educators hypothesized that their one-on-one training sessions offered their older, widowed patients a respite from loneliness. Hence, it was not unusual for those patients to share long and detailed disease and life narratives that far exceeded the information educators required to perform their training. As one educator suggested, "It's their social outlet." Other educators noted that providing an empathetic ear was as much an expectation and valued component of their role as their clinical expertise, particularly for those patients who had grown frustrated with the loss of support and sympathy from friends and family members.

Interpretation of the deliberate confidant role. Educators also served as a deliberate confidant for patients. This meant they purposefully solicited and received personal information as a means for coaching and counseling (Petronio, 2002). As pointed out in Chapter 5, the deliberate confidant role has been interpreted in studies beyond just healthcare and medicine. However, the concept of the deliberate confidant is relevant to this study because it accounted for two provisions, the provision of access and time, and the provision of reciprocating disclosures.

One of the reasons educators were indicative of the deliberate confidant role was because they could provide the type of access and time that was necessary for soliciting and receiving thoughtful and meaningful disclosures. This was important because lack of access and time were variables that educators mentioned as objects of criticism from patients regarding their HCPs. Educators found immense value in their ability to provide the sort of opportunities that nurtured disclosure. In fact, many educators suggested that

the value of an unrushed and thoughtful engagement could not be underestimated for its ability to understand and promote better therapeutic and behavioral outcomes, particularly related to adherence.

The stories and anecdotes from educators who provided education program in patients' homes, similarly reinforced the connection of access and time as foundational to the deliberate confidant role. Educators noted that those situations provided for a more personal connection with patients because of the comfort and safety afforded by the home environment. In turn, that connection cultivated a higher sense of trust and thin boundary permeability, as evident by one educator who stated, "I have a different relationship because I've been in their home."

Chapter 5 also noted that a hallmark of the deliberate confidant role is the expectation of reciprocity of information (Petronio, 2002). The rationale for such action is often referred to as *the norm for reciprocity* which is a term that describes the phenomenon by which an individual who receives information from discloser feels obligated to reciprocate with a matching personal disclosure (Bradac et al., 1978). However, some CPM literature maintains that this norm could prove problematic for the deliberate confidant in a healthcare context; an HCP who reciprocates with personal disclosures to a patient can create an awkward situation for both parties. Specifically, that literature has asserted that, unless an HCP's reciprocating disclosure is contextually or therapeutically relevant, it should be avoided as it can actually impede the ability for an HCP to secure and maintain a requisite trust bond with patients (Petronio, 2002; Petronio et al., 2012). The findings from Chapter 5 suggested that educators believed that, for the most part, patients had few expectations for reciprocating personal

disclosures. For those few educators who did broach the topic, their responses demonstrated alignment with the assertions noted by Petronio as they tried to avoid giving patients personal information about themselves.

Other educators' actions though were representative of Petronio's qualifier of "unless an HCP's reciprocating disclosure is contextually or therapeutically relevant." For example, the proactive self-disclosures of two educators noted in Chapter 5 illustrated the exceptions to the "no reciprocating self-disclosures" rule. Both educators shared stories of how they divulged personal anecdotes to patients regarding their own struggles with disease and health issues. One educator explained that he would tell his patients with diabetes that he also suffered from the Type 1 form of the disease because in doing so, he would "see a totally different level of interaction, alertness, understanding." Similarly, the other educator alluded to the way that her proactive disclosure of her own issues with weight management benefited her patients who were also coping with the problem.

Interpretation of the reluctant confidant role. Educators shared numerous anecdotes and narratives evident of the reluctant confidant role. As Petronio (2002) pointed out, this is an individual who receives private information from a discloser without an expectation for that information. Additionally, she also points out that an HCP who functions as a deliberate or stakeholder confidant can take on a reluctant confidant role when patients disclose information not relevant to their health or the therapeutic context (Petronio & Sargent, 2011). As nurses, clinical educators fell under a subset of reluctant confidants describe by Petronio (2002) as occupational confidants. These are individuals who receive unsolicited or extraneous information as a result of

their occupation. Regardless of the terminology given to the role, in instances of unwanted disclosures, the HCP was left to determine how to manage that extraneous information within the already established privacy rules.

Many of the educators in this study accepted that the disclosure of superfluous and irrelevant information was a byproduct of their role, thus reinforcing their status as occupational confidants (Petronio, 2002). They took it in stride and even made light of some of the peculiar personal narratives patients had provided. Educators who worked mostly with elderly individuals, such as those who educated on the osteoporosis medication, hypothesized these sorts of disclosures happen frequently because their patients were lonely. Hence their reluctant confidant role was co-created from a need for social engagements. Conversely, one of the educators who provided education for terminal neurodegenerative disease patients postulated such disclosures served a therapeutic function.

Earlier in this chapter, three types of ethical dilemmas were discussed in relation to the influence of political/legal context factors that manifested themselves as compliance regulations. Two of those ethical dilemmas, patients versus their families and patients versus their HCPs, can be viewed in the context of the reluctant stakeholder role. Many of the examples from those two types of dilemmas were situations in which a patient disclosed to an educator information about family members or HCPs. If the educators were to have revealed that information to those HCPs or family members, they would be at high risk for damaging the boundary permeability they had with the patient. More so, that disclosure could also harm the boundary permeability between the patient and his/her family and HCP. Petronio and Sargent (2011) conceded this type of

emotional and moral distress in their study of nurses who frequently functioned as reluctant confidants. However, just as Petronio and Sargent acknowledged that the nurses in their study developed various strategies to address such dilemmas, so too did the educators in this project. One tactic mentioned by educators was the "just roll with it" tactic. These educators believed that it was important to not be dismissive of the disclosure of extraneous information while using subtle verbal prompts to get the patient back on track. Others though stressed that in some instances, irrelevant narratives could be counterproductive and therefore, a "cut it off" approach was warranted.

Implications of theme 7. Pharmaceutical-sponsored clinical educators are partners in a unique, paradoxical relationship with patients. Educators are simultaneously a member within, and an outsider to, each patients' healthcare team. They are an "insider" in that they assume a role and legitimize a perception by patients as an investor in their care. This is because educators provided the type of information and educational services that become integral for patients' adherence to therapy as well as for the development of confidence and skills necessary to properly self-manage a disease. Additionally, educators actively solicit, receive, and document personal health information from their patients that is used to support and nurture the achievement of broader health and treatment goals. Conversely, as an outsider to a patient's "formal" healthcare team, educators are not allowed to provide medical advice, are limited in their ability to address certain topics related to the disease or treatment, and cannot access, or even be privy to, a complete medical history. Such barriers can therefore impede educators' ability to deliver the sort of tailored information that is possible when working in the field.

Educators' ability to co-construct different confidant roles speaks to theirs, and their patients', perceptions of them as both insiders and outsiders to the healthcare team. As a stakeholder confidant, they serve mostly as an insider and therefore should continue to abide to the same privacy structures and behaviors they utilized in their field experiences. Based on the responses of most educators in this study, that is already part of their common privacy management practices. However, while many educators approached that role with an assumption of imbued trust, they should continue to be vigilant to the limitations that may carry. As many educators also pointed out, regardless as to whether trust is initially earned or automatically instilled, it can always be lost. Therefore, efforts should always be undertaken to assure trust is maintained. Trust maintenance is a core component of the other two roles, especially given that these roles tend to exist more in the outsider realm. When patients engage educators as a deliberate or reluctant confidant, they do so because they view the educator as providing the sort of time, access, and unwavering ear for disclosure that is not available from their HCP. As such, educators must be sure to set proper expectations with patients as to how those disclosures will be kept private. Yet, they also need to simultaneously impress upon the patient the necessity to share disclosed concerns with their HCP.

Limitation and Future Studies

Limitations. The clinical educators for this study were all selected from a recruitment pool provided by one patient support services company, VMS BioMarketing. While most of those interviewed also had experiences working as clinical educators for VMS competitors or directly with a pharmaceutical company, the VMS commonality did serve as a limiting factor. One way it impacted the study was because of my relationship

with the company; I was a VMS employee at the time interviews were conducted. Even though multiple efforts were taken to assure participants that their confidentiality would be protected, educators may have been apprehensive in providing candid responses to me, particularly those educators employed or under contract with VMS at that time. Even those participants who were no longer employed or under contract with VMS may have felt some reluctance to be fully forthcoming, lest they assume word would get back to VMS and hurt future job prospects.

Another drawback of this study was that some educators limited their responses in a way that was only representative of their VMS experiences, even though they were asked to reflect on the totality of their career as a pharmaceutical-sponsored clinical educator. Had I the ability to interview clinical educators with no prior or current affiliation with VMS, I would have been able to isolate and interpret the data beyond that company's context. This would have generated some insight as to whether the identified themes were salient and relevant to educators regardless of employer. While my role as an "insider" to this study's phenomena of interest proved beneficial on many fronts, these two study weaknesses are examples of the way that role limited collection and analysis of data.

The medium by which data was collected was also a limiting factor. Many of the telephonic educators spoke of the difficulty in not being able to view their patients' body language when conversing with them—a skill they had mastered and found helpful for properly assessing patients when working in their field roles. This was true for this study as well. As all participant data was collected telephonically, I was unable to observe the sort of facial and kinesthetic cues that would have indicated instances of excitement,

boredom, annoyance, etc. during the interview. Hence, while I was able to rely on some verbal and linguistic cues regarding an educator's emotional state, and adjust my line of questioning appropriately, I was not able to account for emotions that manifested themselves via body language and facial expressions.

Future studies. A frequently articulated and debated concept that emerged from the data was the notion of imbued trust, the idea that educators were automatically instilled with a high level of trust based on their HCP credentials. Future studies could explore if educators' perceptions of that construct, as outlined in this study, align in other situations. This could include examining clinical educators' concept of imbued trust as a study, in and of itself, that is more broadscale and which incorporates survey data from a larger population of educators. Along that same line, there is opportunity to explore the question as to whether and how nurses would approach their communication engagements differently if they felt they did not have a high level of trust already imbued in them.

Predisposed trust should also be explored from the patient perspective in which a research focus is understanding how those who engage with clinical educators develop trust relationships. Such studies could be approached from a qualitative perspective that relies on interview data, such as this one, as a means for developing rich understandings regarding the nature of the patient-educator experience. However, a broadscale quantitative or mixed methods approach could also examine the imbued trust phenomenon across large populations to examine the phenomenon within or between demographic, therapeutic, or other ecological factors.

As noted in Chapter 3, an intent for this study was to examine the research questions beyond the domain of a specific program delivery modality, disease state, medication administration method, or educator employment type using a maximum variation sampling strategy. Hence the findings and conclusions that emerged have interpreted the communication experiences of pharmaceutical-sponsored clinical educators with broad thematic strokes. On-going research could now examine educators' experiences within the context of one of the specified domains above. For instance, how do themes that emerge from a study of just diabetes clinical educators align to the ones identified in the study? Does a study that includes only telephonic clinical educators draw similar conclusions as this one? Are the implications the same for educators who have only provided education on self-infusion medications the same as those noted for the broader range of educators here? Additionally, there are even more opportunities for studies that explore how clinical educators engage within different patient demographic factors. This would include studies that examine the educator-patient relationship within the context of a specific characteristics such as gender, race, socioeconomic status, geography, education, or health literacy level.

Lastly, the clinical educator is just one of multiple stakeholders related to the field of pharmaceutical education and coaching. This study examined their views strictly in reference to the patients they served. However, future studies could also examine the communication experiences and relationships educators have with the HCPs with whom they also serve, as well as their relationship with the members of the industry who employ and support their efforts.

Final Thoughts

Prior to my position working for VMS, I had no concept of who a pharmaceutical-sponsored clinical educator was, yet alone what one did. Like many, I am fortunate in that I have not required their services. Over the last six-plus years though, I have gained an appreciation for the unique role they satisfy in an increasingly complex healthcare system. Their relationship with patients as both insiders and outsiders to the formal care team serves as a benefit and a challenge. I surmise that most educators find the position to be a suitable means for fulfilling the altruistic tendencies that drove them to a life of service and care for others. In many ways, the types of connections they develop with patients are as genuine and rewarding as the ones they created when working in hospitals and physicians' offices—for some, even more so.

CPM scholars provide a rationale for how and why patients were quick to establish a strong personal bond with HCPs like clinical educators; patients had an emotional need to disclose feelings and understood that doing so was required to receive health services (Petronio & Sargent, 2011). However, a relevant assertion that can be made is that the educators felt as equally a strong need as their patients for establishing an emotional connection, particularly for those educators who served in a fulltime capacity. The lives of such educators often imitated that of a traveling salesperson, spending long hours in the car, punctuated with short interpersonal exchanges with strangers before heading out on the road to their next stop. Similarly, most telephonic educators worked from home, devoid of personal contact with both patients and their fellow healthcare professionals. Hence, the isolation that is inherent to their jobs, along with the altruistic and empathetic predisposition common among HCPs, could explain why so many of

them believed their responsibilities extended beyond purveying information. Some educators were as emotionally invested in their patients as their patients were invested in them. As one educator stated, “For me, that's the reward, is leaving somebody better than you found them.”

Unfortunately, such statements are typically not part of the narrative that makes the headlines or captures the attention of government regulators as it relates to the services provided by clinical educators. As these sorts of programs increase in popularity, so too does the scrutiny of educators’ responsibilities and expectations. Issues of white coat marketing will continue to pose a concern by those inside and outside the industry. However, though the educators I interviewed struggled with many of the rules that governed their duties, their perspectives were not indicative of the way those compliance regulations impacted their companies’ bottom lines. The educators who engaged in compliance violations always did so from a professional and ethical obligation, not a financial one. Such a moral compass should be held up as an exemplar for an industry that struggles with maintaining the public’s trust.

Chapter 7: Appendices

Appendix A

Recruitment and Participation Communication

Interview Recruitment Email (email #1)

Subject: BE A PART OF A CLINICAL EDUCATOR RESEARCH STUDY!

VMS is excited to announce we are assisting Indiana University Purdue University Indianapolis (IUPUI) in a research study of the experiences of clinical educators who deliver education and coaching services **to patients** on behalf of pharmaceutical and biotech companies. VMS has agreed to provide IUPUI researchers with access to their current and former educators and is encouraging educators to participate. As there is little research that has examined the experiences of healthcare professionals like you who provide these types of services, this study may offer valuable information and insights.

Participation is voluntary and is completely independent of your VMS-related responsibilities. Therefore, your involvement will be completely confidential.

If you would like to participate or would like more information, simply send an email stating so to [email address] by [date]. Use the phrase "Clinical Educator Study" in the subject line.

DO NOT REPLY TO THIS EMAIL.

Thank you,

Tim Barshinger

PhD Candidate IUPUI

Follow-up to Interview Recruitment Email (email #2)

Thank you for your interest in participating in this research project. I want to provide you with some additional information to assist in your decision-making process. My name is Tim Barshinger and I am a PhD candidate in Health Communication at Indiana University Purdue University Indianapolis (IUPUI). This study will provide the data for my dissertation project. I also work for VMS as an instructional designer in the Creative Services Department.

As was shared in the initial email, this study is completely voluntary and will be independent of any client work you do for VMS. You will not be compensated for participating. If you are selected to be interviewed, your involvement will be kept confidential and I will only share the data collected from you with my research team at IUPUI. You will also be given a pseudonym that will be used for data tracking, analysis, and reporting. Additional information about confidentiality protection is included in the attached Study Information Sheet (SIS). Please review the SIS carefully as it also describes in greater detail the study's purpose and potential risks. This project has been approved by the Indiana University Institutional Review Board (IRB).

Participation involves three components:

- **Filling out and returning the attached participant information form**. This should only take a few minutes. This form is to help in the selection of participants and to guide some of the questions that will be asked during the interview. Non-identifying information from the form may also be used as part of data analysis and reporting. If you are not selected to be interviewed, this form will be destroyed.

- **A single, one-on-one interview with me**. This interview should last no more than 45-60 minutes and will be conducted telephonically, via web-conference, or if possible, face-to-face. The interview will be audio recorded and transcribed.
- **Attending and contributing to at least one, but no more than two, focus group discussions approximately 1-3 months after the initial interview**. These meetings should last no more than 60-90 minutes and will also be audio recorded and transcribed.

I am interested in interviewing a broad range of clinical educators from different backgrounds, client networks, disease states, and program delivery modalities. Therefore, not everyone who expresses an interest may be selected to participate. I am also only interviewing educators who have provided pharmaceutical-sponsored education and/or coaching **to patients** at some point in their career. If you have only ever provided pharmaceutical-sponsored education to healthcare providers, I will not be able to interview you.

Additionally, I am wanting to interview educators who are comfortable speaking about how they navigate within compliance guidelines while educating patients. This would include talking with educators who may have experienced adverse event reports from patients, those who may have had to respond to questions or concerns not addressed within the scope of a product label, **and/or** those who may have been asked for personal opinions or for elaborations on a product's risks and benefits. I am also seeking educators who are comfortable discussing how different types of patient demographics, lifestyle factors, and health behaviors influence communication. Finally, I am seeking educators willing to reflect on and discuss the concept of "privacy" as it relates to

information shared by patients. Once again, your identity and responses will NOT be provided to anyone other than the IUPUI researchers. Both the researchers and VMS understand that participants will need to be candid and honest with the information they share.

The next steps:

- Carefully review the attached Study Information Sheet (SIS)
- Fill out the attached participant information form
- Email the completed information form back to me within one week

Once I have received your form, I will contact you and inform you whether you will be interviewed and, if so, to schedule a time to conduct it.

If you have any questions, please don't hesitate to contact me via phone or email. If you decide that you would not like to participate, please respond to this email indicating such.

Thanks so much!

Tim Barshinger

Follow-up to Interview Recruitment Email (email #2-ALTERNATE VERSION)

Hey (name):

Thank you for your interest in participating in this research project. I want to provide you with some additional information to assist in your decision-making process. In addition to working at VMS, I am also a PhD candidate in Health Communication at Indiana University Purdue University Indianapolis (IUPUI). This study will provide the data for my dissertation project. As I shared in the initial email, this study is completely

voluntary and will be independent of any client work you do for VMS. Additionally, as this is an unfunded project, I am unable to compensate you for participating. The primary data collected for this project will be from interviews and focus groups meetings with a representative group of Clinical Educators.

If you are selected to be interviewed, your involvement will be kept confidential and I will only share the data collected from you with my research team at IUPUI. You will also be given a pseudonym that will be used for data tracking, analysis, and reporting. Additional information about confidentiality protection is included in the attached Study Information Sheet (SIS). Please review the SIS carefully as it also describes in greater detail the study's purpose and potential risks. This project has been approved by the Indiana University Institutional Review Board (IRB).

Participation involves three components:

- **Filling out and returning the attached participant information form.** This should only take a few minutes. This form is to help in the selection of participants and to guide some of the questions that will be asked during the interview. Non-identifying information from the form may also be used as part of data analysis and reporting. If you are not selected to be interviewed, this form will be destroyed.
- **A single, one-on-one interview with me.** This interview should last no more than 45-60 minutes and will be conducted telephonically, via web-conference, or if possible, face-to-face. The interview will be audio recorded and transcribed.
- **Attending and contributing to at least one, but no more than two, focus group discussions approximately 1-3 months after the initial interview.**

These meetings should last no more than 60-90 minutes and will also be audio recorded and transcribed.

I am interested in interviewing a broad range of clinical educators from different backgrounds, client networks, disease states, and program delivery modalities. Therefore, not everyone who expresses an interest may be selected to participate. I am also only interviewing educators who have provided pharmaceutical-sponsored education and/or coaching to patients at some point in their career. If you have only ever provided pharmaceutical-sponsored education to healthcare providers, I will not be able to interview you.

Additionally, I am wanting to interview educators who are comfortable speaking about how they navigate within compliance guidelines while educating patients. This would include talking with educators who may have experienced adverse event reports from patients, those who may have had to respond to questions or concerns not addressed within the scope of a product label, and/or those who may have been asked for personal opinions or for elaborations on a product's risks and benefits. I am also seeking educators who are comfortable discussing how different types of patient demographics, lifestyle factors, and health behaviors influence communication. Finally, I am seeking educators willing to reflect on and discuss the concept of "privacy" as it relates to information shared by patients. Once again, your identity and responses will NOT be provided to anyone other than the IUPUI researchers. Both the researchers and VMS understand that participants will need to be candid and honest with the information they share. (See the attached VMS Letter of Support)

The next steps:

- **Carefully review the attached Study Information Sheet (SIS)**
- **Fill out the attached participant information form**
- **Email the completed information form back to me within <u>one week</u>**

Once I have received your form, I will contact you and inform you whether you will be interviewed and, if so, to schedule a time to conduct it.

If you have any questions, please don't hesitate to contact me via phone or email. If you decide that you would not like to participate, please respond to this email indicating such.

Thanks so much!

Tim Barshinger

<u>Focus Group Invitation Email (email #3)</u>

Subject: CLINICAL EDUCATOR RESEARCH STUDY FOLLOW-UP FOCUS GROUP

Hope you are doing well. And thank you again for participating in this research study on the communication experience of pharmaceutical-sponsored clinical educators. As I had shared during the interview, I am reaching out to you again regarding the second part of this study. I would like to have you participate in a [telephonic/web-conference] focus group discussion with other clinical educators who were interviewed. This discussion will serve as a strategy referred to as "member checking" which is a technique by which study participants are asked to review and reflect on some of the initial findings noted by the researchers. I have attached a summary document of those findings that will guide our discussion. Please review it prior to attending. To accommodate

everyone's schedule, I am offering multiple sessions as noted below. **Please respond to this email indicating ALL the sessions you could be available to attend by [date]**. This will help me create similar-sized groups. *You will only be scheduled for one session.*

Yours and the other participants' confidentiality remains an imperative. Therefore, during the discussion I will refer to everyone using their pseudonym and request that you do the same. If you recognize the identity of another participant, I ask that you not divulge that information to anyone else. I have also attached the Study Information Sheet (SIS) that was emailed to you at the start of this project and outlines the purpose, benefits, and risks of this study.

- Your pseudonym is [name].
- The date/time options for focus group sessions are the following: [date/time list]

Once I have received the responses indicating everyone's availability, I will email you with your scheduled date and time along with instructions for connecting to the discussion.

If you have any questions, please don't hesitate to contact me via phone or email.

Thanks so much!

Tim Barshinger

Phone/Voicemail Message for Responders to Initial Email

This is Tim Barshinger. I'm calling as you responded to my email about participating in the research study on clinical educators. First, I want to share my excitement for your interest in participating. Just some information about me. I'm a PhD

candidate in Health Communication at Indiana University and this study will provide the data for my dissertation. So I'm very appreciative of those folks who volunteer their time to help me with this. I also work for VMS as an Instructional Designer.

I just wanted to share some quick points about the study. First, the study includes three parts. The first is filling out a very short form about your background as a clinical educator. The second is participating in a telephone interview with me that will last about 45-60 minutes. The third part is participating in a telephonic focus group with other interviewees a few month a few months after the initial interview.

I'll be sending you an email today that explains this and more in greater detail. The email also will have three attachments. The first is the Indiana University Study Information Sheet which describes the purpose and guidelines of the study, its potential risks and contact information. The second is a letter of support from VMS BioMarketing (not commissioned). The third is the Participant Information form which is the background survey form I'll need you to complete and send back to me if you are interested in participating. If you can get that form back to me ASAP, I'd greatly appreciate it.

If you decide you would not like to participate, that is absolutely fine. I'd just ask if you would call or email me to let me know.

If you have any questions, don't hesitate to contact me. And once again, thank you so much for your interest. I'm looking forward to speaking with you.

Tim

Appendix B

Study Information Sheet

INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR

Interpretations of Communication Experiences of Pharmaceutical-Sponsored Clinical Educators

You are invited to participate in a research study of how pharmaceutical-sponsored clinical educators communicate with, and interpret, their experiences with patients. You were selected as a possible subject because of your role as a current or former pharmaceutical-sponsored clinical educator. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Timothy Barshinger and Dr. Jennifer Bute of Indiana University Purdue University Indianapolis' Department of Communication Studies. Timothy is also an employee of VMS BioMarketing.

STUDY PURPOSE

The purpose of this study is to gain insight as to how pharmaceutical-sponsored clinical educators—individuals who provide medication and disease education on behalf of pharmaceutical companies—communicate with patients. This study may help the pharmaceutical industry understand how regulatory requirements can influence patients' adherence goals. It may also assist the industry by identifying weaknesses of the pharmaceutical-sponsored clinical educator model and providing recommendations to address them. Finally, this study may be valuable to the policy makers who create the guardrails that regulate these programs.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will do the following things:

- **A.** You will fill out a short participant information form. This should only take a few minutes. This form is to help in the selection of participants and to guide some of the questions that will be asked during the interview. Non-identifying information from the form may also be used as part of data analysis and reporting. If you are not selected to be interviewed, this form will be destroyed.
- **B.** You will participate in a one-on-one interview with a researcher that will last approximately 45-60 minutes. Your interview may be conducted face-to-face, telephonically, or via web-conference. All interviews will be audio recorded and then transcribed. Timothy and/or a professional transcription service will complete the transcriptions. If a service is use, Timothy will review the transcriptions for accuracy and remove identifiable information prior to analysis. The interview will occur in late 2018 or early 2019. The purpose of the interview is to gather background information, discuss experiences with patient interventions, and explore conversation dynamics as well as provide you an opportunity to offer insights and recommendations regarding education programs.

C. You will also participate in at least one, but no more than two, focus group discussions with other interviewed participants. The first focus group will occur within the first four months of 2019 and will be conducted telephonically or via a web-conference. It will last approximately 60-90 minutes and will be audio recorded and transcribed. The purpose of the first focus group is to have you review and reflect on of some of the initial findings noted by the researchers. If the focus groups' interpretations are discordant to the findings and extensive reanalysis of the data occurs, then you may be asked to participate in a second focus group meeting a few months later.

RISKS AND BENEFITS

A risk of participating in this research is being uncomfortable answering questions posed during the interview questions and during the focus group meeting/s.

There is also a risk of loss of confidentiality.

You are not expected to directly benefit from participating in this research. However, the analysis of the data collected from you may be used to help inform and guide other patient educator programs, including those of your employer or contracting organization.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. Tape and/or video recordings of interviews will only be accessible to the researchers and will be destroyed within one year following the completion of the study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigators and their research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP).

PAYMENT

You will not receive payment for taking part in this study.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study, contact the researcher Jennifer Bute at (###) ###-#### or Timothy Barshinger at (###) ###-####.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (###) ###-#### or (###) ###-####.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with VMS BioMarketing.

Appendix C

VMS Letter of Support

vms BioMarketing

Educate. Empower. Repeat.

Indiana University Institutional Review Board

November 20, 2018

To Whom It May Concern:

I am pleased to provide Timothy Barshinger, a VMS BioMarketing employee, and his IU faculty advisor Dr. Jennifer Bute, permission to conduct Tim's dissertation research project at our site as part of his requirements for his PhD in Health Communication. I understand that Tim will be interviewing representatives of our clinical educator programs at various intervals from now until the Spring of 2019. In fact, Tim has discussed his research plan with myself on multiple occasions, as well as with our Chief Financial Officer, and the head of our Compliance Department who have all signed off on the project.

VMS understands that clinical educator participation is completely voluntary and that participants may choose to quit the project at any time for any reason. We also understand that educators will receive a Study Information Sheet that explains their rights and responsibilities for participating. Tim will provide a copy of that sheet to us as well to have on file once it has been approved by you.

We recognize that participating educators will need to provide honest and candid responses as part of the interview process. Tim has shared with us the plan to protect the confidentiality and integrity of those interviews. We have agreed to support those measures. We understand that no VMS employee, other than Tim, will know the identity of the interviewed clinical educators.

We're very excited for this opportunity for Tim and Dr. Bute. While we see the immediate value of this project for VMS, we also recognize its larger importance in the area of patient empowerment and better self-management of chronic conditions.

If you have any questions, please don't hesitate to contact me.

Regards,

Abby Mallon
Sr. Vice President of Innovation and Chief Compliance Officer

501 Pennsylvania Parkway, Suite 100 Indianapolis, IN 46280 p: 317.805.6600 f: 317.805.6650 vmsbiomarketing.com

Appendix D

Participant Information Form

Participant Information Form

INSTRUCTIONS: Fill out the following information by entering text in the text fields and by clicking in the appropriate boxes. When answering questions, consider all ***patient*** education programs you have provided on behalf of a pharmaceutical or biotech company, including those not done with VMS BioMarketing. Save the completed form as a new file that includes your name. Return to Tim Barshinger at [redacted]. For questions, call Tim at [redacted]

FIRST & LAST NAME

CITY & STATE

PHONE

GENDER ☐ Male ☐ Female

AGE RANGE ☐ < 30 ☐ 30-45 ☐ 46-60 ☐ > 60

EMPLOYMENT STATUS WITH VMS BIOMARKETING (check all that apply)

☐ current employee ☐ former employee

☐ active contractor/non-VMS-employee ☐ inactive or former contractor/non-VMS-employee

PROFESSIONAL CREDENTIALS (check all that apply)

☐ RN ☐ PharmD ☐ RD ☐ PA ☐ NP ☐ MD/DO ☐ LCSW ☐ other:

NUMBER OF YEARS DELIVERING PATIENT/CAREGIVER EDUCATION PROGRAMS ON BEHALF OF PHARMACEUTICAL OR BIOTECH COMPANIES

☐ < 1 ☐ 1-2 ☐ 3-5 ☐ 6-10 ☐ > 10

LANGUAGES IN WHICH YOU HAVE DELIVERED PATIENT/CAREGIVER EDUCATION PROGRAMS ON BEHALF OF PHARMACEUTICAL OR BIOTECH COMPANIES (check all that apply)

☐ English ☐ Spanish ☐ other:

MODALITIES IN WHICH YOU HAVE DELIVERED PATIENT/CAREGIVER EDUCATION PROGRAMS ON BEHALF OF PHARMACEUTICAL OR BIOTECH COMPANIES (check all that apply)

☐ 1:1 face-to-face ☐ group face-to-face ☐ telephonic ☐ web-conference/videoconference

☐ SMS/texting to mobile ☐ instant message/chat ☐ other:

TYPES OF PATIENT/CAREGIVER EDUCATION PROGRAMS YOU HAVE DELIVERED ON BEHALF OF PHARMACEUTICAL OR BIOTECH COMPANIES (check all that apply)

☐ product education ☐ disease-state/lifestyle education

MEDICATION ADMINISTRATION TYPES FOR WHICH YOU HAVE DELIVERED PATIENT/CAREGIVER EDUCATION PROGRAMS ON BEHALF OF PHARMACEUTICAL OR BIOTECH COMPANIES (check all that apply)

☐ oral ☐ self-injection: syringe ☐ self-injection: pen/auto-injector ☐ self-infusion

☐ HCP-administered (e.g. office, infusion center) ☐ N/A ☐ other:

DISEASES FOR WHICH YOU HAVE DELIVERED PATIENT/CAREGIVER EDUCATION PROGRAMS ON BEHALF OF PHARMACEUTICAL OR BIOTECH COMPANIES (check all that apply)

☐ T1 diabetes ☐ T2 diabetes ☐ Crohn's disease ☐ ulcerative colitis ☐ osteoporosis ☐ psoriasis

☐ rheumatoid arthritis ☐ psoriatic arthritis ☐ ankylosing spondylitis ☐ hyperlipidemia ☐ ALS

☐ dementia ☐ schizophrenia ☐ bipolar disorder ☐ primary immunodeficiency

☐ other:

Appendix E

Interview Guides

Interview Guide

Note: Indented questions will serve as additional "prompts" that will only be used when/if needing to probe for more detailed information.

1. Before we begin, I first need to verify that you are not currently engaged in any sort of legal dispute or action related to patient and/or healthcare provider education services with VMS Biomarketing, or a pharmaceutical company, biotech company, or any company that offers similar services as VMS.
2. Briefly summarize your background as a health professional (timeline).
3. Reflect back on your training, tell me what you recall about learning HOW to communicate with patients?
    a. Did you take any structured courses, seminars, or workshops about patient-provider communication?
    b. Compare your training on clinical skills with training on interpersonal/communication skills.
    c. How would you compare the importance of clinical skills with the importance of interpersonal & communication skills for nursing?
4. Tell me about your previous experience teaching and/or coaching patients when you worked in the field (e.g. doctor's office, hospital, pharmacy, etc)?
    a. How did you come about working for these programs?
    b. How were those engagements initiated?

    c. What conversations were stressful, challenging, or uncomfortable to have with patients?
    d. What strategies did you use to overcome or lessen that stress and anxiety?
5. Tell me about any organizational structures or guardrails that guided or directed the training and coaching conversations you had with patients.
6. As you talk with patients, you often gain insights into their lives. Does this knowledge ever impact or change how you talk with them or deliver the education program? How so?
7. What role does "trust" play in patient education?
8. What role does "privacy" play in patient education
9. The rest of the questions are going to be in regard to your experiences delivering patient education that has been sponsored by on conducted on behalf of a pharmaceutical or biotech company. Tell me about the programs for which you provide service? (VMS and non-VMS related)
    a. Tell me about the materials and resources that you use.
    b. Tell me about the system you use to capture data.
10. What parts of the program excite you the most?
11. What parts of the program frustrate you the most?
12. Let's talk about HOW you talk with patients during these programs. Tell me about the way you determine what to say to patients and how to say it.
13. Tell me about the role or nature of compliance regulations in your programs?
14. Do compliance regulations make your job harder? How so? (Presented with an off-label question)

15. Tell me what an adverse event, or a reportable event, is and how it affects communication or patient education?
16. Let's revisit the concept of "trust" we talked about earlier. Tell me about the nature of this concept "trust" as it relates to how you deliver a pharmaceutical-sponsored program.
17. Let's revisit the concept of "privacy" we talked about earlier. Tell me about the nature of this concept "privacy" as it relates to how you deliver a pharmaceutical-sponsored program.
18. If you had a respected colleague from the field who has a similar background and great passion toward patient education tell you s/he was thinking about becoming a pharmaceutical educator, what would you say to them?
19. I had an educator, when answering that question, explain to me that when she first told her colleagues that she was taking a job as a pharmaceutical educator, they said to her "So you're going to the dark side". Have you experienced anything similar? Why do you think they said that? How did/would you respond then? How about now?
20. What changes or recommendations would you offer to VMS and/or the pharmaceutical companies you work with?

OPTIONAL

21. Throughout the program, you have asked patients to set goals, tell me more about those goals and how you help the patient determine suitable ones.
    a. How do patients react when asked to create goals?
    b. How do you respond to those reactions?

22. How do you go about getting a patient to enroll in the programs?
    a. What do you believe are some the reasons patients choose to enroll in the Program?
    b. What do you believe are some of the reasons patients choose not to enroll?
    c. Do you feel you have a sense at the start of the first conversation whether or not a patient will enroll?
23. *[For programs involving a self-injected biologic]* The medication you discuss with patients is a self-injectable biologic. Self-administering an injectable on a regular basis would seem stressful or anxiety-producing for some patients. Tell me what verbal cues you listen for to help you identify whether a patient has anxiety about self-injecting.
    a. What communication strategies have you found to be most helpful when speaking with a patient you perceive to be anxious about self-injecting?
    b. Tell me how the script guides help and/or hinder your ability to have these conversations.
24. Tell me if you ever feel like you know a patient is going to benefit or succeed with a program? What are the indicators? (Feel free to provide examples)
    a. Why do you think they will benefit or succeed?
    b. What qualities or characteristics do they possess that make you believe this?
25. Tell me if you ever feel like you know a patient is NOT going to benefit or succeed with a program? What are the indicators? (Feel free to provide examples)

a. Why do you think they won't benefit or succeed?

b. What qualities or characteristics do they possess that make you believe this?

26. Take a moment to reflect on the conversations you have had so far with those two patients. In what ways is your conversation different between them?

    a. How might have you use different words or phrases?

    b. How might have you clarified, elaborated, or probed with each?

    c. How might have their language or responses influenced your words and actions?

27. Compare the conversations you have with the program patients to patients in your other positions.

    a. In what ways are they similar?

    b. In what ways are they different?

    c. Do you feel program conversations are easier, harder, or no different than other types of patient conversations? Explain why.

28. The primary goal for your programs is to provide information and support for patients that encourages them to stay on their medication. Would you agree with that? Are there other goals and how do they compare to the one I mentioned?

    a. How do the script guides support you for reaching those goals?

    b. How do the script guides hinder you in reaching those goals?

    a. Would you prefer more structure, less structure, or no change to the scripts? Why?

29. Do you feel program conversations are easier, harder, or no different than other types of patient conversations?

Interview Guide-2nd Wave

Note: Indented questions will serve as additional "prompts" that will only be used when/if needing to probe for more detailed information.

1. Before we begin, I first need to verify that you are not currently engaged in any sort of legal dispute or action related to patient and/or healthcare provider education services with VMS Biomarketing, or a pharmaceutical company, biotech company, or any company that offers similar services as VMS.
2. Briefly summarize your background as a health professional (timeline).
3. Tell me how you would interpret the term "authentic nursing" (or "authentic healthcare providing" for non-RNs).
4. Reflect back on your training, tell me what you recall about learning HOW to communicate with patients?
5. Tell me about your previous experience teaching and/or coaching patients when you worked in the field (e.g. doctor's office, hospital, pharmacy, etc)?
6. As you talk with patients, you often gain insights into their lives. Does this knowledge ever impact or change how you talk with them or deliver the education program? How so?
7. What role does "trust" play in patient education?
8. What role does "privacy" play in patient education
9. The rest of the questions are going to be in regard to your experiences delivering patient education that has been sponsored by on conducted on behalf of a

pharmaceutical or biotech company. Tell me about the programs for which you provide service? (VMS and non-VMS related)

10. What parts of the program excite you the most?
11. What parts of the program frustrate you the most?
12. Tell me about the role or nature of compliance regulations in your programs?
13. Do compliance regulations make your job harder? How so? (Presented with an off-label question)
14. Tell me some of the strategies, or tactics, you use to navigate through or around compliance regulations.
15. Tell me what an adverse event, or a reportable event, is and how it affects communication or patient education?
16. Let's revisit the concept of "trust" we talked about earlier. Tell me about the nature of this concept "trust" as it relates to how you deliver a pharmaceutical-sponsored program.
17. Let's revisit the concept of "privacy" we talked about earlier. Tell me about the nature of this concept "privacy" as it relates to how you deliver a pharmaceutical-sponsored program.
18. Have you ever been in a situation or had a feeling like you were caught between your loyalty to a patient and your loyalty to the pharma company? How about between the patient and his/her HCP or family member?
19. At the beginning of our conversation, I asked you to explain the concept of "authentic nursing" Do you consider what you do as a pharma-sponsored clinical educator to fit within that definition?

20. Do the patients you work for consider what you do to be authentic nursing? The HCPs you work with? The pharmaceutical company/clinical educator services provider (i.e. VMS)?
21. If you had a respected colleague from the field who has a similar background and great passion toward patient education tell you s/he was thinking about becoming a pharmaceutical educator, what would you say to them?
22. I had an educator, when answering that question, explain to me that when she first told her colleagues that she was taking a job as a pharmaceutical educator, they said to her "So you're going to the dark side". Have you experienced anything similar? Why do you think they said that? How did/would you respond then? How about now?
23. What changes or recommendations would you offer to VMS and/or the pharmaceutical companies you work with?

OPTIONAL

24. Throughout the program, you have asked patients to set goals, tell me more about those goals and how you help the patient determine suitable ones.
    c. How do patients react when asked to create goals?
    d. How do you respond to those reactions?
25. How do you go about getting a patient to enroll in the programs?
    d. What do you believe are some the reasons patients choose to enroll in the Program?
    e. What do you believe are some of the reasons patients choose not to enroll?

f. Do you feel you have a sense at the start of the first conversation whether or not a patient will enroll?

26. *[For programs involving a self-injected biologic]* The medication you discuss with patients is a self-injectable biologic. Self-administering an injectable on a regular basis would seem stressful or anxiety-producing for some patients. Tell me what verbal cues you listen for to help you identify whether a patient has anxiety about self-injecting.

    c. What communication strategies have you found to be most helpful when speaking with a patient you perceive to be anxious about self-injecting?

    d. Tell me how the script guides help and/or hinder your ability to have these conversations.

27. Tell me if you ever feel like you know a patient is going to benefit or succeed with a program? What are the indicators? (Feel free to provide examples)

    a. Why do you think they will benefit or succeed?

    b. What qualities or characteristics do they possess that make you believe this?

28. Tell me if you ever feel like you know a patient is NOT going to benefit or succeed with a program? What are the indicators? (Feel free to provide examples)

    a. Why do you think they won't benefit or succeed?

    b. What qualities or characteristics do they possess that make you believe this?

29. Take a moment to reflect on the conversations you have had so far with those two patients. In what ways is your conversation different between them?
    a. How might have you use different words or phrases?
    b. How might have you clarified, elaborated, or probed with each?
    c. How might have their language or responses influenced your words and actions?
30. Compare the conversations you have with the program patients to patients in your other positions.
    a. In what ways are they similar?
    b. In what ways are they different?
    c. Do you feel program conversations are easier, harder, or no different than other types of patient conversations? Explain why.
31. The primary goal for your programs is to provide information and support for patients that encourages them to stay on their medication. Would you agree with that? Are there other goals and how do they compare to the one I mentioned?
    c. How do the script guides support you for reaching those goals?
    d. How do the script guides hinder you in reaching those goals?
    b. Would you prefer more structure, less structure, or no change to the scripts? Why?
32. Do you feel program conversations are easier, harder, or no different than other types of patient conversations?

Appendix F

Interview Guides

Focus Group Discussion Guide

Interpretations of Communication Experiences of Pharmaceutical-Sponsored Clinical Educators

Abstract: This study explores the communication experiences of clinicians who provide patient education and coaching services on behalf of a pharmaceutical sponsor. I am investigating how these clinical educators interpret their role and how they navigate a medical encounter within the domain of three regulatory drivers—on-label compliance, fair-balance presentation, and adverse event reporting. I am using the ecological model of communication in medical encounters and the theory of Communication Privacy Management (CPM) as the lenses for designing the study and interpreting the data. Specifically, I am investigating how the three regulatory drivers function as a type of organizational context within the ecological model and thereby influences the conversation dynamics between clinical educators and patients. Additionally, I am exploring the concept of the clinical educator experience within the context of three CPM confidant roles—deliberate confidant, stakeholder confidant, and reluctant confidant. Finally, I am examining how the regulatory drivers may impact the boundary permeability of the patient-educator relationship. Outcomes from this study will provide insight as to how pharmaceutical-sponsored clinical educators communicate with patients. As more pharmaceutical companies enlist the assistance of clinical educators for patient education services, and a growing number of patients are utilizing them to receive health information and make healthcare decisions, studies such as this one are

necessary. This study will assist the pharmaceutical industry in understanding that the regulatory requirements that function as ecological drivers for these programs can influence the programs' adherence goals. Additionally, this study will help the industry by identifying other weaknesses of the pharmaceutical-sponsored clinical educator model and provide recommendations to address them.

Research Questions

RQ1: How do ecological factors, such as regulatory requirements, function within pharmaceutical-sponsored clinical educators' communication with patients?

RQ2: How do those ecological factors influence the way pharmaceutical-sponsored clinical educators establish and manage communication privacy boundaries with patients?

About the Interview Process

A total of twenty-six clinical educators were interviewed for this study in two waves. The first wave of seventeen interviews took place in January and February. The second wave of nine interviews occurred in May and June. Transcripts from the first wave were coded in March and April. This preliminary analysis led to emergent ideas and themes that were further refined or explored in the second wave. Therefore, some interview questions were changed, added, or omitted for the second wave.

About the Participants

All twenty-six clinical educators were recruited from VMS' rosters of current and former employees and contractors. A few of the twenty-six educators served at one point as both an employee and a contractor. In addition, most educators had current or previous experience in a pharmaceutical-sponsored clinical educator role beyond VMS.

Some educators even had prior experiences working for pharmaceutical companies as a sales rep or in other roles. All interviewed educators had prior field-based clinical healthcare experience such as working in a hospital, clinic, or physician's office. The majority of clinical educator's delivered programs that included multiple engagements or sessions with patients (face-to-face or telephonically) though a few noted their pharmaceutical educator experiences consisted primarily of a single intervention (i.e. "one and done"). Some other statistics about the group:

- All but two participants were female
- Two had delivered programs in Spanish. Everyone had delivered programs in English
- Educators were geographically diverse with 9 from the Midwest, 6 from the Southeast, 3 from the Northeast, 3 from the Southwest, 3 from the West Coast, and 2 from the Mountain West
- Half of participants were in the age range of 46-60, 8 were over 60, and 5 were 30-45
- 22 were RNs, 2 were RDs, 2 were NPs, 2 were MScNs, 1 was MEd, 1 was LN, 1 was MPH, and 11 were CDEs
- 12 had between 3-5 years' experience delivering pharma programs, 8 had over 10 years, and 6 had 6-10 years
- 23 had experience providing pharma-sponsored education for a self-injectable syringe and/or pen, 10 for orally-administered drugs, 9 for self-infusion drugs, and 12 for HCP-administered

- 15 educators had experience providing pharma-sponsored education for T2 diabetes, 12 educators for T1 diabetes, 11 educators for osteoporosis and psoriasis, 10 educators for psoriatic arthritis, 9 educators for ankylosing spondylitis, 6 educators for Crohn's disease and rheumatoid arthritis, 5 educators for ulcerative colitis, 4 educators for hyperlipidemia, ALS, and primary immunodeficiency, 3 educators for MS.

About the Theories

Ecological Model of Communication in the Medical Encounter

This model explains how ecological factors influence the nature and scope of interpersonal patient-provider dialogue within a medical encounter. Proponents of this model typically segment these factors into four contexts of socio-political and demographic factors that impact both the patient and the HCP and the way their interactions unfold. The **culture context** is comprised of factors such as race, gender, ethnicity, religion, geography, education, socioeconomic status, and family dynamics. The **media context** includes factors such mass media exposure as well as access to, and use of, the Internet and telemedicine. The **organizational context** includes the influence of structures such as managed cared, the medical services available, and the standards of care that drive those services. The **political-legal** context is inclusive of factors that are tied to governments' influence is healthcare such as the Affordable Care Act (ACA), HIPAA, government-funded healthcare programs (e.g. Medicare, Medicaid), malpractice litigation, and patients' bill of rights.

Communication Privacy Management (CPM) Theory

CPM asserts that individuals believe they maintain ownership over their private information and the way others can access it. Individuals develop their own set of privacy rules as the means for maintaining control and management of the information. These rules manifest themselves in figurative boundaries that vary in terms of thickness. "Thickness" is a metaphor akin to the concept of boundary permeability that describes the degree of trust an individual is willing to provide to another person regarding the type and amount of disclosed information. Thick boundaries are considered impermeable as they represent high levels of restriction to information while thin boundaries are viewed as permeable with fewer constraints. However, CPM theory goes on to state that once information is disclosed to another person, that information in now co-owned with the recipient. The recipient and discloser may then establish the privacy rules regarding the sharing of that information. The recipient is responsible for abiding to those privacy rules. If the recipient violates those rules, whether purposefully or because of miscommunication or misinterpretation, privacy turbulence occurs. When this happens, boundary permeability between the discloser and recipient might change and new privacy rules might be established. CPM notes that recipients of private information are often assigned one of four types of confidant roles by the discloser, three of which are relevant to this study—deliberate, reluctant, and stakeholder.

- Deliberate confidant: an individual who is disclosed private information because it is actively solicited, such as in the case of a counseling, therapy, or education
- Reluctant confidant: an individual who receives private information, intentionally or inadvertently, but did not have an expectation for such

- Stakeholder confidant: an individual, such as doctors, nurses, and other patient-facing health professional who, by nature of their healthcare role, receive patients' private health information

Discussion Guide for Emerging Themes

Theme 1: Clinical educator interpretation of their role identity is rooted in their experiences.

Insights

As all educators had prior field experience, the pharmaceutical-sponsored clinical educator role was defined in relationship to that field role.

While all educators identified themselves within the construct of "pharmaceutical-sponsored clinical educator," there were variant interpretations of that role based on such factors as patients' disease journey-type (e.g. terminal disease vs. chronic), communication modality (e.g. all telephonic), shared disease experiences, and prior experience as a pharma sales rep.

Theme 2: While educators were mostly consistent in their interpretation of the concept of "authentic nursing" or "authentic healthcare providing", there was wide discrepancy as to whether they felt their role as a pharmaceutical-sponsored clinical educator would fall within that interpretation.

Insights

"Authentic" was typically discussed within a context of providing hands-on clinical care, open communication, exhibiting the characteristics of empathy and respect, and creating a relationship built on trust.

Educators who felt they were not practicing "authentic nursing" or "authentic healthcare providing" pointed to such factors as their inability to provide clinical care or offer medical advice, a lack of access to patient medical records, the impact of compliance regulations (e.g. unable to address off-label questions), or a limited number of opportunities to engage the patient (e.g. "one and done")

While there was inconsistency among educators in the way they viewed the authenticity of their role, most educators felt that patients and some HCPs perceived the pharmaceutical-sponsored clinical educator to be an authentic healthcare provider.

There was also inconsistency among educators as to whether the pharmaceutical industry, particularly sales reps, viewed them as authentic healthcare providers.

What is your view of "authentic nursing"/ "authentic healthcare providing" as it relates to the pharmaceutical-sponsored clinical educator role? Why is this a relevant question to be asking?

Theme 3: The four contexts of ecological factors—culture, media, organizational, and political-legal—influence how a clinical educator communicates with patients.

Insights

Educators most-frequently identified culture context factors—age, race, religion, gender, geography, SES, language, education, and family/community dynamics—as they

were related to the patient. The exception to this was "age" which was also identified as being influential as it related to the educator.

Within the media context, educators identified influential factors such as health literacy and media literacy as well as patients' experiences using telephonic and on-line communication resources.

Within the organizational context, educators overwhelmingly noted that health insurance navigation and related medication access bureaucracy impacted communication and education.

The political-legal context was discussed within the domain of government and industry-imposed compliance regulations related to factors such as on-label compliance, fair-balance presentation, and adverse event reporting.

There was discrepancy as to whether compliance regulations made the clinical educator job more difficult. What are your views? Is the answer to this question found on a strict dichotomy ("yes" or "no") or as notches on a continuum? Is it situationally related?

Theme 4: A fifth context, not previously identified in the ecological model literature, emerged from the interviews as having significant influence in the conversation dynamics between the educator and patient. This is the **disease context**.

Insights

Throughout the interviews, educators frequently referenced how the nature of the disease itself and/or its treatments and therapies were highly influential in how they would communicate with and educate a patient.

The types of factors educators identified that could fit within a disease context include: chronic or terminal prognosis, disease side effects, treatment side effects, pregnancy status (as it related to disease or treatment side effects), drug administration modality (e.g. oral, self-injectable, etc.), prevalence of disability or comorbidity, and where the patient was on their disease journey.

Theme 5: When educating patients, educators accommodate many, but not all, ecological factors as they have multiple context-specific strategies they use. Within the political-legal context, they have learned how to compliantly navigate within regulatory structures through "nuanced" communication tactics.

Insights

A common tactic for addressing compliance-related factors was "deferment"—typically redirecting those patient questions or concerns they felt they were not allowed to answer, back to the patient's HCP.

While educators noted that deferment could sometimes frustrate patients, most educators used communication strategies to help abate that frustration.

A development of "rapport" and "trust" was frequently described as a necessary precursor for navigating patients through ecological factors that served as barriers to disease management.

Theme 6: The nature of the clinical educator role, such as the impact of compliance regulations on communication, occasionally forced educators to experience ethical dilemmas.

Insights

A sense of "dual loyalty"—a conflicting loyalty to the patient to provide the best care possible and to the sponsoring pharmaceutical company to deliver a compliant program—was noted as a challenging aspect of the clinical educator role.

Some educators explained that patients sometimes view clinical educators as a surrogate for their physician and will even disclose frustration or negative information about the physician and their office staff. Educators also noted that physicians have even provided information to patients that would be incorrect or inconsistent with the product label. This can create a tension among the physician, patient, and clinical educator relationships.

While educators understand the rationale for "scripted" programs, many regarded them to be overly scripted and therefore a hindrance and a source of frustration. Is going off script ever "ok", such as in a situation in which a patient is inattentive or not grasping the concepts as they are presented? Do you think pharmaceutical companies give tacit approval for this?

Theme 7: When discussing how patient disclose private information, educators described patient behaviors indicative of all three types of confidant roles—deliberate, reluctant, and stakeholder. However, educators tended to use descriptors and language more aligned to a deliberate confidant role, as opposed to a stakeholder confidant role, to **define** their communication relationships with patients.

Insights

Earning trust was noted to be one of the most (if not, the most) important factor necessary for establishing a confidant relationship with a patient.

Some educators felt that a public perception of nurses as a trust-worthy profession helped initially imbue them with a level of trust necessary to outweigh any negative perceptions related to their affiliation with the pharmaceutical industry.

The concept of "meeting the patient where they are at" was a frequent refrain in the interviews. What does this mean as it relates to confidant roles? Is it always possible in the pharmaceutical-sponsored clinical educator role?

Appendix G

Codebook

First-level Codes

#	CODE	LONG NAME/S	DEFINITION	RELATED CODES
1	Abandon	Abandon/s	Refers to a Pt quitting or discontinuing participating in CE services or programs	Accessible, Adherence, Barrier, Distrust, DrugScrutiny, Fail, Fear, PtEcon, Safety, Stress, Unprep,
2	AboveBey	Above and Beyond	Describes or refers to CE or HCP efforts that go beyond the usual	Balance, CDE, CERole, Connect, DiffMaker, EngagePts, Excites, Holistic, LovePts, PtShoes, Satisfaction, Support, Workaround,
3	Accept	Accept/s/ance	Related to Pt accepting an explanation or information provided by CE or HCP	Adherence, AgeImpact, Connect, DisDefine, EngagePts, Goals, Motivator, Protect, PtEcon, Respect, SavingFace, SelfManage, TrustEarned, TrustHCP, TrustRelate, Validate,
4	Accessible	Accessible/ility	Related to ability for Pt to access education, medication or health services	Abandon, Adherence, BehavChng, Boundaries, Connect, Enroll, HealthInfo, Holistic, InfoSeek, Insurance, LangLit, Navigate, ProgBene, Support,
5	Accountable	Accountable	Describes or refers to holding Pt or CE accountable for their actions	Adherence, Goals, HCPRelate, Liability, Metric, RelateDyna, SelfAdvocate, SelfManage, TrustEarned,
6	Adherence	Adherence	Refers to adherence or ability to follow therapy regimens prescribed by HCP	Abandon, Accept, Accessible, Accountable, AgeImpact, Barrier, BehavChng, Behavior, Fail, Fear, Frustration, Goals, Inject, Insurance, LangLit, Motivator, Navigate, PtEcon, PtKnow, PtSavvy, SelfManage, SideEffect, Strategies, Stress, Support,

7	AE	Adverse Event/s	Refers to an adverse event within the context of compliance regulations	Barrier, Comorbid, CompRegs, Death, DrugAdmin, DrugScrutiny, FairBal, Inject, Liability, OnLabel, PharmaTrust, Protect, Report, Safety, SideEffect, Undocumented,
8	AgeImpact	Age Impact	Describes or refers to how a Pt's age influences or impacts their behavior or education	Accept, Adherence, AssessPts, Barrier, BehavChng, Behavior, CommSkills, Connect, Counsel, Culture, DiscCE, DrugAdmin, EdFam, EngagePts, ExpLimit, FamCare, FamDyna, Holistic, LangLit, ModImpact, PersEx, PtKnow, PtSavvy, RelateDyna, SelfAdvocate, SelfManage, Support, Tailoring, Misconcept,
9	AgeValue	Age Value	CE explaining the value, or drawback, of their age in education	CDE, CERole, CommSkills, Counsel, Empathy, ExpLimit, FldVPharm, PersEx, ProfDev, Rapport, RelateDyna,
10	AssessPts	Assessing/ment of Patients	Refers to or describes manner in which CE assesses a patient for education	AgeImpact, Barrier, CERole, Counsel, Data, Holistic, LangLit, Metric, Misconcept, PtKnow, Strategies, Tailoring, Validate,
11	Authentic	Authentic/ity	Related to or demonstrating an "authentic" interpretation of nursing and/or healtcare	
12	AutoImm	Auto Immune Disease/s	Related to auto immune diseases or conditions	CERole, ChronDis, Comorbid, DisDefine, DisState, DrugAdmin, HIV, Infusion, RareDis, TermDis,
13	Autonomy	Autonomy/ous	Describes or refers to patient autonomy	
14	Balance	Balance/s/ing/ed	Refers to CE instance or expectation to balance competing needs of Pt and HCP	AboveBey, CEIndep, EngagePts, FairBal, FldVPharm, LovePts, OpenComm, PersEx, PrivManage, ProtoBreach, RelateDyna, SavingFace, TrustDef, TrustRelate,

15	Barrier	Barrier/s	Describes or refers to those things that impede education for Pt or CE	Abandon, Accessible, Adherence, AE, AgeImpact, AssessPts, BehavChng, Culture, Depress, DiscBarr, Distrust, ExpLimit, Fail, Fear, Frustration, Goals, Insurance, LangLit, Misconcept, Motivator, NoVoice, PtEcon, SavingFace, SelfManage, Stress, Support, TrustSac, Unprep,
16	BehavChng	Behavior Change/s	Describes or refers to the process of changing Pt behavior	Adherence, AgeImpact, Barrier, Behavior, EngagePts, Goals, InfoSeek, Misconcept, Motivator, Navigate, PersEx, PtKnow, PtLeads, PtSavvy, Satisfaction, SelfManage, Strategies,
17	Behavior	Behavior/s	Describes or refers to behaviors within the the context of Pt disease or education	Adherence, AgeImpact, BehavChng, Rapport, SavingFace, SelfAdvocate, SelfManage, Stress, TrustSac,
18	Boundaries	Boundaries	Related to a CE or Pt setting guidelines or guardrails related to education	Accessible, CompRegs, FairBal, HCPFeedback, OnLabel, OpenComm, PrivManage, Protect, RelateDyna, Respect, Script, Security, Sensitive, TrngProc, Unethical, UninhibDisc,
19	Cardiac	Cardiac	Related to the heart, heart disease, or cardiac care	CERole, ChronDis, Comorbid, Death, DisDefine, DisState, DrugAdmin, RareDis, TermDis,
20	CDE	Certified Diabetes Educator	Describes or refers to a certified diabetes educator	AboveBey, AgeValue, CEBenefit, CEIndep, CERole, Diabetes, Dietitian, FldVPharm, PharmaRep, ProfDev,
21	CEBenefit	Clinical Educator Benefit/s	Refers to a benefit of being a CE	CDE, CEIndep, CERole, DiffMaker, EngagePts, Excites, LovePts, Motivator, ProgBene, Respect, Satisfaction, Teach,

22	CEIndep	Clinical Educator/s Independence	Related to CE demonstrating independence from influence of HCP or Pharma Co.	Balance, CDE, CEBenefit, CERole, FairBal, FldVPharm, HCPFeedback, NoVoice, PharmaTrust, PrivBreach, PrivManage, ProgReco, Protect, TrustBreach, TrustRelate,
23	CERole	Clinical Educator/s Role/s	Refers to a CE describing, defining, or interpreting their role or the things they do	AboveBey, AgeValue, AssessPts, AutoImm, Balance, Cardiac, CDE, CEBenefit, CEIndep, Counsel, Demo, DiffMaker, DiscCE, Empathy, EngagePts, ExpLimit, FairBal, Holistic, ICU, Inject, LovePts, Motivator, Notekeeping, Oncology, Osteo, PersEx, PrivRole, ProfDev, ProgReco, Protect, Teach, TeleEd, TrustRelate,
24	ChronDis	Chronic Disease/s	Refers to a chronic disease	AutoImm, Cardiac, Comorbid, Diabetes, DisDefine, DisState, HIV, Neuro, Oncology, Osteo, Parkinsons, RareDis, SideEffect, TermDis,
25	CommInhibit	Communication Inhibit/s/ion	Related to communication that is inhibited	CommSkills, CompExcess, CompImpact, CompRegs, Defer, DiscBarr, DiscCE, DiscFacil, Distrust, LangLit, Liability, Misconcept, OpenComm, PrivBreach, Sensitive, Support, TrustBreach, UninhibDisc,
26	CommSkills	Communication Skill/s	Highlights, explains or defines a communication skill relevant to Pt. education	AgeImpact, AgeValue, CommInhibit, Connect, Counsel, Defer, DiscFacil, Empathy, EngagePts, FairBal, FTF, LangLit, ModImpact, Notekeeping, OnLabel, OpenComm, PrivManage, ProfDev, Rapport, RelateDyna, Strategies, Support, Tailoring, Teach, TrngProc, TrustRelate, WebEd,
27	Community	Community/ies	Describes or refers to a Pt's community or how that community impacts Pt education	Culture, EdFam, FamDyna, PersEx, PrivFam, Support,

28	Comorbid	Comorbidity/ies	Describes or refers to health conditions other than disease of interest	AE, AutoImm, Cardiac, ChronDis, Depress, Diabetes, DisState, ICU, Oncology, Osteo, Parkinsons,
29	CompExcess	Compliance Excess/es/iveness	Related to instance or interpretation of compliance regs being excessive	CommInhibit, CompImpact, Defer, Distrust, DrugScrutiny, Frustration, Liability, OnLabel, PharmaTrust, PharmaOps, PrivBreach, PrivManage, Protect, Report, Safety, TeleLimit, TrustBreach, Undocumented,
30	CompImpact	Compliance Impact/s/ing	Describes or refers to how compliance regs have a (+ or --) effect or impact	CommInhibit, CompExcess, CompRegs, Defer, Distrust, FairBal, Frustration, Liability, OnLabel, PharmaTrust, PharmaOps, PrivManage, Protect, Report, Safety, Sensitive, Stress, TrngProc, TrustBreach,
31	CompRegs	Compliance Regulation/s	Describes or refers to compliance regulations	AE, Boundaries, CommInhibit, CompExcess, CompImpact, Consent, FairBal, Liability, OnLabel, Metric, Notekeeping, PharmaOps, PrivManage, Protect, Report, Security, SideEffect, TrngProc, Workaround,
32	Connect	Connect/s/ion/ed	Refers to CE and Pt making an relationship connections	AboveBey, Accept, Accessible, AgeImpact, CommSkills, DiffMaker, DiscCE, Empathy, FTF, HandlingLoss, Holistic, HCPRelate, LangLit, LovePts, OpenComm, Rapport, RelateDyna, Respect, SelfManage, Support, TrustDef, TrustEarned, TrustRelate, UninhibDisc, Validate,
33	Consent	Consent/s/ing	Refers to obtaining or honoring Pt consent as it relates to a CE, HCP, or ed. Program	CompRegs, Counsel, EngagePts, HCPConsent, Inject, LangLit, Liability, PharmaOps, PrivBreach, PrivManage, Protect, ProtoBreach, SelfManage, TrustPriv,

34	Consistency	Consistency/ies	Related to maintaining consistency as related to the Pt education process	FairBal, Metric, Rapport, Script, SelfManage, TrngProc, Unprep,
35	Counsel	Counsel/s	Related to the process or manner in which an CE or HCP counsels a Pt.	AgeImpact, AgeValue, AssessPts, CEBenefit, CERole, CommSkills, Consent, DrugAdmin, EngagePts, FamCare, FTF, Holistic, Inject, LangLit, Navigate, PtLeads, PtShoes, Rapport, RelateDyna, Respect, SelfManage, Support, Tailoring, TeleEd, TrngProc, TrustRelate, Validate,
36	Culture	Culture/s/al	Related to the role or impact of culture on Pt education	AgeImpact, Barrier, Community, Distrust, EdFam, FamCare, HealthInfo, LangLit, Misconcept, PharmaTrust, PrivRole, PtShoes, Rapport, Respect, Sensitive, Support, Tailoring, TrustRelate, Workaround,
37	Data	Data	Refers to Pt data or information that is gathered by the CE or HCP	AssessPts, Enroll, Goals, HealthInfo, Materials, Metric, Notekeeping, Report, Satisfaction, Undocumented,
38	Death	Death	Related to experiences or references of death	AE, Cardiac, Depress, Desperate, DisState, Fear, HandlingLoss, ICU, Oncology, RareDis, Suicide, TermDis,
39	Defer	Defer/s/ment/ments	Related to the manner in which a CE must defer a Pt to their HCP for info.	CommInhibit, CommSkills, CompExcess, CompImpact, DiscCE, Distrust, Frustration, Navigate, OnLabel, PharmaTrust, PharmaOps, SavingFace, Strategies, TrustSac, Workaround,
40	Demo	Demonstration/s	Related to a CE performing a demonstration or patient giving return demo	CERole, DrugAdmin, EngagePts, FTF, Infusion, Inject, Materials, PtKnow, PtLeads, Strategies, TrngProc,

41	Depress	Depression/Depressing	Refers to descriptions or actions of Pt related to depression	Barrier, Comorbid, Death, Desperate, DisDefine, Fail, Fear, HandlingLoss, NoVoice, SideEffect, Stress, Suicide, TermDis,
42	Desperate	Desperate	Related to a sense of desperation from the patient or CE	Death, Depress, Fear, Frustration, HandlingLoss, Manipulating, PtEcon, RareDis, Stress, Suicide, TermDis, Unprep,
43	Diabetes	Diabetes	Describes or refers to diabetes	CDE, ChronDis, Comorbid, DisState,
44	Dietitian	Dietitian	Related to the role or profession of dietitian or dietitics	CDE, PersEx, ProfDev,
45	DiffMaker	Difference Maker	Describes or refers to when or how a CE making a difference or wanting to make one	AboveBey, CEBenefit, CERole, Connect, Empathy, EngagePts, Excites, Goals, Holistic, LovePts, NoVoice, ProgBene, RelateDyna, Satisfaction, Support, TrustRelate,
46	DiscBarr	Disclosure Barrier/s	Describes or refers to barriers or factors that inhibit disclosures by Pts	Barrier, CommInhibit, DiscCE, DiscFacil, Distrust, FamDyna, Fear, Frustration, HCPRelate, LangLit, Misconcept, ModImpact, NoVoice, PharmaTrust, PrivBreach, PrivSet, ProtoBreach, Rapport, RelateDyna, SavingFace, Sensitive, Support, TeleLimit, TelePriv, TrustBreach, TrustPriv, TrustRelate,
47	DiscCE	Discloses/ing/ure to Clinical Educator	Describes or refers to how/when a Pt (or family) discloses private information to CE	AgeImpact, CERole, CommInhibit, Connect, Defer, DiscBarr, DiscFacil, EngagePts, FamCare, FamDyna, FTF, Holistic, LangLit, Misconcept, PrivManage, PrivRole, PtLeads, Rapport, TrustEarned, TrustPriv, TrustRelate, UninhibDisc,
48	DiscFacil	Disclosure Facilitator/s	Describes or refers to things factors that facilitate or encourage disclosures by Pts	CommInhibit, CommSkills, DiscBarr, DiscCE, EngagePts, Goals, Holistic, LangLit, LovePts, Motivator, OpenComm, PrivSet, PtSavvy,

				Rapport, RelateDyna, Support, TelePriv, TrustEarned, TrustPriv, TrustRelate, UninhibDisc,
49	DisState	Disease State	Refers to information or education related to a Pt's disease	AutoImm, Cardiac, ChronDis, Comorbid, Death, Diabetes, DisDefine, HealthInfo, HIV, ICU, Neuro, Oncology, Osteo, Parkinsons, PtKnow, RareDis, TermDis,
50	DisDefine	Disease Define/s/ed/ing	Refers to notion that Pts' diseases defines who they are	Accept, AutoImm, Cardiac, ChronDis, Depress, DisState, Empathy, Fear, HIV, LangLit, NoVoice, Oncology, Osteo, PersEx, PtKnow, PtShoes, Rapport, RareDis, SavingFace, Stress, TermDis, Validate,
51	Distrust	Distrust/s/ing	Describes or refers to instance or sense of distrust	Abandon, Barrier, CommInhibit, CompExcess, CompImpact, Culture, Defer, DiscBarr, DrugScrutiny, Fear, Frustration, HCPRelate, Misconcept, Manipulating, PharmaTrust, PrivBreach, ProtoBreach, RelateDyna, SelfManage, Sensitive, Stress, TrustBreach, Unethical,
52	DrugAdmin	Drug Administration/s	Describes or refers to the process of administering a drug to a Pt.	AE, AgeImpact, AutoImm, Cardiac, Counsel, Demo, DrugScrutiny, FairBal, ICU, Infusion, InHome, Inject, Materials, Misconcept, Oncology, OnLabel, Osteo, PharmaCo, PharmaOps, PharmaRep, Safety, Stress, TrngProc, Unprep,
53	DrugScrutiny	Drug Scrutiny	Related to scrutiny of a drug by an HCP, CE or Pt.	Abandon, AE, CompExcess, Distrust, DrugAdmin, HCPRelate, Infusion, Inject, PharmaCo, PharmaTrust, Pregnant, Safety, SideEffect, TrustBreach, TrustHCP, TrustRelate,

54	EdFam	Education of Family	Related to the education of a patient's family, caregivers, etc.	AgeImpact, Community, Culture, FamCare, FamDyna, InHome, Navigate, PrivFam, PrivSet, Support, Tailoring, TrngProc, TrngSet,
55	Efficacy	Efficacy/ies	Describes or is related to the efficacy or benefits of treatment	
56	Empathy	Empathy	Describes or is related to the showing of empathy by the CE or Pt	AgeValue, CERole, CommSkills, Connect, DiffMaker, DisDefine, EngagePts, FamCare, HandlingLoss, HCPRelate, Holistic, LovePts, Motivator, PtShoes, Rapport, RelateDyna, SavingFace, Sensitive, Support, TrustDef, TrustEarned, TrustHCP, TrustRelate,
57	EngagePts	Engaging Patient/s	Refers to or describes manner in which patients are engaged in education	AboveBey, Accept, AgeImpact, Balance, BehavChng, CEBenefit, CERole, CommSkills, Consent, Counsel, Demo, DiffMaker, DiscCE, DiscFacil, Empathy, FTF, Goals, HCPEngage, HCPRelate, Holistic, LangLit, ModImpact, OpenComm, PrivManage, PtKnow, PtLeads, Rapport, RelateDyna, Respect, Satisfaction, SelfManage, Strategies, TrngProc, TrustDef, TrustEarned, TrustRelate,
58	Enroll	Enroll/s/ing/ment	Related to the process of getting Pts enrolled in a pharma education service/program	Accessible, Data, HCPConsent, Inject, Notekeeping, PtEcon, TrngProc, Undocumented,
59	EthDilemma	Ethical Dilemma/s	Refers to an ethical dilemma faced by CE related to Pt care	
60	Excites	Excite/s/ing/ed	Describes or refers to things that are, or may, excite a CE about his/her role	AboveBey, CEBenefit, DiscBarr, Goals, LovePts, PersEx, Satisfaction,

61	ExpLimit	Experience Limitation/s	Describes or refers to CE or HCP being limited in ability because of lack of experience	AgeImpact, AgeValue, Barrier, CERole, PersEx, ProfDev, Teach, TrustRelate, Unprep,
62	Fail	Fail/s/ure/ures	Refers to Pt or CE inability to accomplish task or goal related to health	Abandon, Adherence, Barrier, Depress, Fear, Frustration, Manipulating, NoVoice, PtKnow, SelfManage, Stress, TeleLimit, Unprep,
63	FairBal	Fair Balance	Related to requirement that CE must present balance of efficacy and risk in education	AE, Balance, Boundaries, CEIndep, CERole, CommSkills, CompImpact, CompRegs, Consistency, DrugAdmin, FldVPharm, Frustration, LangLit, Liability, Materials, OnLabel, PharmaOps, PharmaOps, Report, Safety, Script, SideEffect, Strategies, TrngProc,
64	FamCare	Family Care/ing	Describes or refers to the manner in which a CE cares for the family as well as Pt.	AgeImpact, Community, Counsel, Culture, DiscCE, EdFam, Empathy, FamDyna, InHome, LangLit, Navigate, Pregnant, PrivFam, PrivSet, PtKnow, RelateDyna, Strategies, Support, TrngProc, TrngSet, TrustEarned,
65	FamDyna	Family Dynamic/s	Describes or refers to how family dynamics impact or come into play in education	AgeImpact, DiscBarr, DiscCE, EdFam, FamCare, Fear, Frustration, HandlingLoss, InHome, LangLit, Misconcept, Motivator, Pregnant, PrivSet, PtEcon, PtShoes, RelateDyna, SavingFace, SelfAdvocate, SelfManage, Stress, UninhibDisc,
66	Fear	Fear/s	Related to role or impact of fear on Pt or CE	Abandon, Adherence, Barrier, Death, Depress, Desperate, DiscBarr, DisDefine, Distrust, Fail, FamDyna, Frustration, Misconcept, NoVoice, Pregnant, PrivBreach, Safety, Sensitive, Stress, Suicide, TermDis, TrustBreach, Validate,
67	FldVPharm	Field Versus Pharma	Comparison of CE experiences or education	AgeValue, Balance, CDE, CEIndep, FairBal, OnLabel, PharmaCo, PharmaOps, PrivRole,

			delivery in the field versus as pharma rep	ProgBene, ProgReco, Rapport, RelateDyna, Tailoring, TrngSet,
68	Frustration	Frustration/s	Related to CE or Pt's frustration with drug or education process	Adherence, Barrier, CompExcess, CompImpact, Defer, Desperate, DiscBarr, Distrust, Fail, FamDyna, Insurance, Misconcept, PharmaTrust, PtEcon, Stress, TeleLimit, TrustBreach, Unethical, Unprep,
69	FTF	Face-to-Face	Describes or refers to Pt education programs delivered live and in-person	CommSkills, Connect, Counsel, Demo, DiscCE, EngagePts, ModImpact, PrivSet, TeleEd, TimeImpact, TrngSet, WebEd,
70	Goals	Goals	Describes or refers to goals or goal setting by the Pt or CE	Accept, Accountable, Adherence, Barrier, BehavChng, Data, DiffMaker, DiscFacil, EngagePts, Excites, Fear, Holistic, InfoSeek, Metric, Navigate, ProfDev, PtSavvy, SelfAdvocate, SelfManage, Strategies, Support, Tailoring, TrngProc, TrustRelate, Workaround,
71	HandlingLoss	Handling Loss	Related to references or descriptions by CE of how they handle Pt death	Connect, Death, Depress, Desperate, Empathy, FamDyna, LovePts, Navigate, OpenComm, RelateDyna, Strategies, Support, TermDis, Validate,
72	HCPConsent	Healthcare Provider Consent	Refers to when or how an HCP provides a consent or permission to a Pt or CE	Consent, Enroll, HCPEngage, HCPFeedback, HCPRelate, PrivManage, RelateDyna, TrustHCP,
73	HCPEngage	Healthcare Provider/s Engagement/s	Related to how a CE engages or interacts with an HCP	EngagePts, HCPConsent, HCPFeedback, HCPRelate, OpenComm, RelateDyna, Respect, Support, TimeImpact, TrustHCP,
74	HCPFeedback	Healthcare Provider Feedback	Related to CE providing feedback to an HCP regarding a Pt.	Boundaries, CEIndep, HCPConsent, HCPEngage, HCPRelate, PrivManage, PrivRole, Protect, RelateDyna, Report, Satisfaction, TrustHCP,

75	HCPRelate	Healthcare Provider/s Relationship/s	Describes or refers to relationships created between Pts and HCPs or CEs and HCPs	Accountable, Connect, DiscBarr, Distrust, DrugScrutiny, Empathy, EngagePts, HCPConsent, HCPEngage, HCPFeedback, Holistic, OpenComm, PrivManage, Rapport, RelateDyna, Satisfaction, Support, TrustHCP,
76	HealthInfo	Health Information	Related to the sources for, use of, or search for health information by Pt	Accessible, Culture, Data, DisState, FairBal, InfoSeek, LangLit, Materials, Misconcept, PtKnow, Security, Strategies, Support,
77	HIV	HIV	Related to HIV/AIDS	AutoImm, ChronDis, DisState, DisDefine, TermDis,
78	Holistic	Holistic	Refers to a holistic approach as related to patient care	AboveBey, Accessible, AgeImpact, AssessPts, CERole, Connect, Counsel, DiffMaker, DiscCE, DiscFacil, Empathy, EngagePts, Goals, HCPRelate, InfoSeek, LovePts, Motivator, Navigate, OpenComm, PtKnow, Rapport, RelateDyna, Respect, Strategies, Support, Tailoring, TrngProc, TrustRelate, UninhibDisc, Unprep,
79	ICU	Intensive Care Unit	Related to experiences or work in the ICU	CERole, Comorbid, Death, DisState, DrugAdmin, TermDis,
80	InfoSeek	Information Seeking	Describes or refers to information seeking processes or behaviors by Pts or CEs	Accessible, BehavChng, Goals, HealthInfo, Holistic, LangLit, Misconcept, Navigate, OpenComm, PtKnow, PtSavvy, Security, SelfAdvocate, SelfManage, Tailoring, TimeImpact, Unprep,
81	Infusion	Infusion/s	Referencing or related to giving/receiving an infusion or the infusion process	AutoImm, Demo, DrugAdmin, DrugScrutiny, InHome, Inject, PharmaCo, RareDis, TermDis,

82	InHome	In-home	Refers to education or engagement that occur in the patient's home	DrugAdmin, EdFam, FamCare, FamDyna, Infusion, Inject, PrivSet, Tailoring, TrngSet,
83	Inject	Injection/Injection Training/s	Related to the process or occurrence of an injection or injection training	Adherence, AE, CERole, Consent, Counsel, Demo, DrugAdmin, DrugScrutiny, Enroll, Fear, Infusion, InHome, Misconcept, OnLabel, PharmaCo, SelfManage, Strategies, Stress,
84	Insurance	Insurance/s	Related to health insurance companies or their policies, procedures, or actions	Accessible, Adherence, Barrier, Frustration, Protect, PtEcon, Stress,
85	LangLit	Language and Literacy	Describes or refers to the relationship among language, literacy, and education	Accessible, Adherence, AgeImpact, AssessPts, Barrier, CommInhibit, CommSkills, Connect, Consent, Counsel, Culture, DiscBarr, DiscCE, DiscFacil, DisDefine, EngagePts, FairBal, FamCare, FamDyna, HealthInfo, Holistic, InfoSeek, Misconcept, ModImpact, Navigate, NoVoice, OpenComm, PrivManage, PtKnow, PtLeads, PtSavvy, Rapport, RelateDyna, SelfAdvocate, Support, Teach, TrustHCP, UninhibDisc,
86	Liability	Liability/ies	Describes or refers to a professional or legal liability for the CE or HCP	Accountable, AE, CommInhibit, CompExcess, CompImpact, CompRegs, Consent, FairBal, Manipulating, Notekeeping, OnLabel, PrivBreach, ProtoBreach, Safety, Undocumented, Unethical, Workaround,
87	LovePts	Love Patients	Related to examples or experiences of CE loving their work with Pts	AboveBey, Balance, CEBenefit, CERole, Connect, DiffMaker, DiscFacil, Empathy, Excites, HandlingLoss, Holistic, PersEx, PtShoes, RelateDyna, Respect, Satisfaction, TrustEarned, TrustRelate,

88	MalePersp	Male Perspective/s	Describes or refers to experiences or perspectives of male CEs	
89	Manipulating	Manipulating	Refers to manipulating or deceitful behaviors	Desperate, Distrust, Fail, Liability, Misconcept, PharmaTrust, TrustBreach, Unethical,
90	Materials	Materials	Refers to physical or electronic resource and materials used in patient ed.	Data, Demo, DrugAdmin, FairBal, HealthInfo, InfoSeek, Metric, OnLabel, Script, Strategies, Tailoring, TrngProc,
91	Metric	Metric/s	Related to metrics or assessments for measuring success or impact of Pt education	Accountable, AssessPts, CompRegs, Consistency, Data, Goals, Materials, ModImpact, ProgReco, PtKnow, Strategies, TrngProc,
92	Misconcept	Misconception/s	Related to a Pt's health misconception and the impact on education or disease	AssessPts, Barrier, BehavChng, CommInhibit, Culture, DiscBarr, DiscCE, Distrust, DrugAdmin, FamDyna, Fear, Frustration, Frustration, InfoSeek, Inject, LangLit, Manipulating, NoVoice, PersEx, PtKnow, SelfManage, Stress, Unprep, AgeImpact,
93	ModImpact	Modality/ies Impact	Describes or refers to impact on Pt education related to communication modality	AgeImpact, CommSkills, DiscBarr, EngagePts, FTF, LangLit, Metric, ProtoBreach, Script, Tailoring, TeleEd, TeleLimit, TelePriv, TimeImpact, TrngProc, WebEd, Workaround,
94	Motivator	Motivator/s	Related to factors or things that are motivate or are motivating for a Pt or CE	Accept, Adherence, Barrier, BehavChng, CEBenefit, CERole, DiscFacil, Empathy, FamDyna, Holistic, OpenComm, Pregnant, ProgBene, PtEcon, PtSavvy, RelateDyna, Respect, Satisfaction, SelfManage, Strategies, Support, TrustEarned, TrustRelate, Validate,
95	MS	Multiple Sclerosis	Related to Multiple Sclerosis	

96	Navigate	Navigate/s/ion/ing	Describes or refers to how a Pt navigates through their disease or the health system	Accessible, Adherence, BehavChng, Counsel, Defer, EdFam, FamCare, Goals, HandlingLoss, Holistic, InfoSeek, LangLit, OnLabel, PersEx, PrivManage, PtLeads, PtSavvy, SelfAdvocate, Support, TrngProc, TrustRelate, Workaround,
97	Neuro	Neurology/Neurologist/s	Related to neurologist or neurology field	ChronDis, DisState, Parkinsons, RareDis, TermDis,
98	NonEng	Non-English Speaking	Describes or refers to non-English speaking Pts and their education	
99	NonVerbal	Non-Verbal	Describes or refers to non-verbal language related to Pt education	
100	Notekeeping	Notekeeping	Refers to CE documentation of Pt information	CERole, CommSkills, CompRegs, Data, Enroll, Liability, Report, Strategies, Undocumented,
101	NoVoice	No Voice	Refers to the notion that the patient has no voice (or no say) in their healthcare	Barrier, CEIndep, Depress, DiffMaker, DiscBarr, DisDefine, Fail, Fear, LangLit, PrivBreach, PrivRole, RelateDyna,
102	Oncology	Oncology/ist	Related to oncology, cancer, or cancer care	CERole, ChronDis, Comorbid, Death, DisDefine, DisState, DrugAdmin, Misconcept, RareDis, SideEffect, TermDis,
103	OnLabel	On-label	Describes or refers to a CE's requirement to remain on-label	AE, Boundaries, CommSkills, CompExcess, CompImpact, CompRegs, Defer, DrugAdmin, FairBal, FldVPharm, Inject, Liability, Materials, Navigate, PharmaCo, PharmaOps, Protect, ProtoBreach, Script, SideEffect, TrngProc, Workaround,
104	OpenComm	Open Communication	Related to a desire for, example of, or definition for unfettered communication	Balance, Boundaries, CommInhibit, CommSkills, Connect, DiscFacil, EngagePts, HandlingLoss, HCPEngage, HCPRelate,

				Holistic, InfoSeek, LangLit, Motivator, PrivManage, Rapport, Respect, SelfManage, TimeImpact, UninhibDisc,
105	Osteo	Osteoporosis	Describes or refers to osteoporosis	CERole, ChronDis, Comorbid, DisDefine, DisState, DrugAdmin, RareDis,
106	Palliative	Palliative	Describes or refers to palliative or end-of-life care	
107	Parkinsons	Parkinson's Disease	Related to Parkinson's Disease	ChronDis, Comorbid, DisState, Neuro, TermDis,
108	PersEx	Personal Experience/s	A personal experience that impacted or influenced a CE or Pt.	AgeImpact, AgeValue, Balance, BehavChng, CERole, Community, DisDefine, Dietitian, Excites, ExpLimit, LovePts, Misconcept, Navigate, Pregnant, ProfDev, ProgReco, PtKnow, PtShoes, Rapport, TrustRelate, Validate,
109	PharmaCo	Pharmaceutical Company/ies	Describes or relates to a pharmaceutical company	DrugAdmin, FldVPharm, Infusion, Inject, OnLabel, PharmaTrust, PharmaOps, PharmaRep, ProgReco, Teach,
110	PharmaTrust	Pharmaceutical Trust/s/ing Distrust	Related to a Pt or HCP feelings of trust or distrust of pharma companies	AE, CEIndep, CompExcess, CompImpact, Culture, Defer, DiscBarr, Distrust, DrugScrutiny, Frustration, Manipulating, PharmaCo, PharmaOps, PharmaRep, PrivBreach, Safety, SideEffect, TrustBreach, Unethical,
111	PharmaOps	Pharmaceutical Operation/s	Describes or refers to operational processes or procedures of a pharma company	CompExcess, CompImpact, CompRegs, Connect, Defer, DrugAdmin, DrugScrutiny, FairBal, FldVPharm, OnLabel, PharmaCo, PharmaTrust, PharmaRep, ProgReco, Report, TrngProc,

112	PharmaRep	Pharmaceutical Representative/s	Referencing or related to a pharma rep	CDE, DrugAdmin, PharmaCo, PharmaOps, PharmaTrust,
113	Pregnant	Pregnant/ancy	Related to pregnancy and it's impact in education or use of a therapy	DrugScrutiny, FamCare, FamDyna, Fear, Motivator, PersEx, Stress,
114	PrivBreach	Privacy Breach/es/ing	Describes or refers to occurrence (or potential for) privacy breach between Pt & CE	CEIndep, CommInhibit, CompExcess, Consent, DiscBarr, Distrust, Fear, Liability, NoVoice, PharmaTrust, PrivManage, ProtoBreach, TrustBreach, TrustSac, Unethical,
115	PrivFam	Privacy Family	Refers to privacy concerns or management with Pt family involvement	Community, EdFam, FamCare, PrivManage, PrivSet, PtLeads,
116	PrivManage	Privacy Management	Describes or refers to strategies or processes for managing privacy	Balance, Boundaries, CEIndep, CommSkills, CompExcess, CompImpact, CompRegs, Consent, DiscCE, EngagePts, HCPConsent, HCPFeedback, HCPRelate, LangLit, Navigate, OpenComm, PrivBreach, PrivFam, PrivRole, PrivSet, RelateDyna, Security, SelfManage, Sensitive, Strategies, TelePriv, TrustBreach, TrustEarned, TrustPriv,
117	PrivRole	Privacy Role/s	Describes or refers to the role privacy plays in Pt education	CERole, Culture, DiscCE, FldVPharm, HCPFeedback, NoVoice, PrivManage, PrivSet, Protect, Security, Sensitive, TrustPriv,
118	PrivSet	Privacy Setting/s	Refers to impact or role of a physical setting on privacy concerns or management	DiscBarr, DiscFacil, EdFam, FamCare, FamDyna, FTF, InHome, PrivFam, PrivManage, PrivRole, TeleEd, TelePriv, TrngSet,
119	ProfDev	Professional Development	Describes or refers to a CE's professional development opportunities or experiences	AgeValue, CDE, CERole, CommSkills, Dietitian, ExpLimit, Goals, PersEx, Tailoring, Teach, Workaround,

120	ProgBene	Program Benefit	Describes or refers to a benefit of Pt education program.	Accessible, CEBenefit, DiffMaker, FldVPharm, Motivator, ProgReco, PtKnow, PtLeads, PtSavvy, SelfAdvocate, SelfManage, Support, TrustEarned, Validate, Workaround,
121	ProgReco	Program Recommendation/s	Describes or refers to CEs' recommendations to improve Pt or HCP programs	CEIndep, CERole, FldVPharm, Metric, PersEx, PharmaCo, PharmaOps, ProgBene, Satisfaction, TrngProc,
122	Protect	Protect/s/ing/ion/ed	Refers to action or process a CE takes to protect a Pt	AboveBey, AE, Boundaries, CEIndep, CERole, CompExcess, CompImpact, CompRegs, Consent, FairBal, HCPFeedback, Insurance, OnLabel, PrivRole, Report, Safety, Security, TrustEarned, Workaround,
123	ProtoBreach	Protocol Breach/es/ing	Describes or refers to a breach of protocol or process related to Pt education	Balance, Consent, DiscBarr, Distrust, Liability, ModImpact, OnLabel, PrivBreach, TeleLimit, TrustBreach, TrustSac,
124	PtEcon	Patient/s Economics	Describes or refers to the role or impact of a patient's personal finances	Abandon, Accept, Adherence, Barrier, Desperate, Enroll, FamDyna, Frustration, Insurance, Motivator, PtSavvy, SelfManage, Stress, Support,
125	PtKnow	Patient/s Knowledge	Refers to existing or necessary Pt knowledge related to their disease or therapy	Adherence, AgeImpact, AssessPts, BehavChng, Demo, DisDefine, DisState, EngagePts, Fail, FamCare, FamDyna, HealthInfo, Holistic, InfoSeek, LangLit, Metric, Misconcept, PersEx, ProgBene, PtSavvy, Satisfaction, SelfManage, Validate,
126	PtLeads	Patient Lead/s/ing	Describes or refers to example or instance of Pt taking the lead in their care or educ.	BehavChng, Counsel, Demo, DiscCE, EngagePts, LangLit, Navigate, PrivFam, ProgBene, PtSavvy, RelateDyna, SavingFace, SelfAdvocate, SelfManage, Support, Tailoring,

127	PtSavvy	Patient/s Savvy/iness	Related to Pt's ability to navigate or understand complexity of health info or processes	Adherence, AgeImpact, BehavChng, DiscFacil, Goals, InfoSeek, LangLit, Motivator, Navigate, ProgBene, PtEcon, PtKnow, PtLeads, SavingFace, SelfAdvocate, SelfManage,
128	PtShoes	Patient Shoes	Refering to a CE putting themselves in their patients' shoes to gain understanding	AboveBey, Counsel, Culture, DisDefine, Empathy, FamDyna, LovePts, PersEx, Rapport, RelateDyna, Respect, Strategies, TrustDef, Validate,
129	Rapport	Rapport	Describes or refers to relationship rapport between Pt and CE or Pt and HCP	AgeValue, Behavior, CommSkills, Connect, Consistency, Counsel, Culture, DiscBarr, DiscCE, DiscFacil, DisDefine, Empathy, EngagePts, FldVPharm, HCPRelate, Holistic, OpenComm, PersEx, PtShoes, RelateDyna, Respect, Satisfaction, SelfManage, TrustDef, TrustEarned, TrustRelate,
130	RareDis	Rare Disease/s	Refers to a rare disease	AutoImm, Cardiac, ChronDis, Death, Desperate, DisDefine, DisState, Infusion, LangLit, Neuro, Oncology, Osteo, TermDis,
131	RelateDyna	Relationship Dynamic/s	Describes or refers to relationship dynamics between CE and Pt or CE and HCP	Accountable, AgeImpact, AgeValue, Balance, Boundaries, CommSkills, Connect, Counsel, DiffMaker, DiscBarr, DiscFacil, Distrust, Empathy, EngagePts, FamCare, FamDyna, FldVPharm, HandlingLoss, HCPConsent, HCPEngage, HCPFeedback, HCPRelate, Holistic, LangLit, LovePts, Motivator, NoVoice, PrivManage, PtLeads, PtShoes, Rapport, Respect, Satisfaction, Support, TrustDef, TrustRelate,
132	Report	Report/s/ing	Refers to a CE or HCP need to create or deliver a reportable event	AE, CompExcess, CompImpact, CompRegs, Data, FairBal, HCPFeedback, LovePts,

				Notekeeping, PharmaOps, Protect, Safety, SideEffect, Suicide, Undocumented,
133	Respect	Respect/s/ing/ed	Describes instances or examples that demonstrate respect among CEs, Pts, and HCPs	Accept, Boundaries, CEBenefit, Connect, Counsel, Culture, EngagePts, HCPEngage, Holistic, Motivator, OpenComm, PtShoes, Rapport, RelateDyna, TrustDef, TrustHCP, TrustRelate, Validate,
134	Safety	Safety	Refers to a CE describing a situation or event in which Pt safety is at risk	Abandon, AE, CompExcess, CompImpact, DrugAdmin, DrugScrutiny, FairBal, Fear, Liability, PharmaTrust, Protect, Report, SideEffect, Stress, Suicide, Unethical, Unprep,
135	Satisfaction	Satisfaction	Refers to Pts or HCPs satisfaction with the services or programs provided by a CE	AboveBey, BehavChng, Data, DiffMaker, EngagePts, Excites, HCPFeedback, HCPRelate, LovePts, Motivator, ProgReco, PtKnow, Rapport, RelateDyna, SelfManage, Support, Tailoring, TrustEarned, TrustRelate,
136	SavingFace	Saving Face	Describes or refers to how a CE or Pt attempts to save face	Accept, Balance, Barrier, Behavior, Defer, DiscBarr, DisDefine, Empathy, FamDyna, PtLeads, PtSavvy, SelfAdvocate, TrustSac, Unprep, Workaround,
137	Script	Script/s	Related to scripts or scripting of program utilized by CE within Pt education programs	Boundaries, Consistency, FairBal, OnLabel, Materials, ModImpact, Strategies, Tailoring, TeleEd, TeleLimit, TrngProc, WebEd,
138	Security	Security	Refers to manner in which CE protects or secures Pt information	Boundaries, CompRegs, HealthInfo, InfoSeek, PrivManage, PrivRole, Protect, Sensitive, Strategies,
139	SelfAdvocate	Self Advocate/s/ing/y	Refers to process or manner in which a Pt must advocate for him/herself	Accountable, AgeImpact, Behavior, FamDyna, Goals, InfoSeek, LangLit, Navigate, ProgBene, PtLeads, PtSavvy, SavingFace, SelfManage, Support, TrustEarned, TrustRelate,

140	SelfManage	Self Manage/s/ing/ment	Refers to process or manner in which a Pt self-manages their health	Accept, Accountable, Adherence, AgeImpact, Barrier, BehavChng, Behavior, Connect, Consent, Consistency, Counsel, Distrust, EngagePts, Fail, FamDyna, Goals, InfoSeek, Inject, LangLit, Misconcept, Motivator, OpenComm, PrivManage, ProgBene, PtEcon, PtKnow, PtLeads, PtSavvy, Rapport, Satisfaction, SelfAdvocate, Strategies, Support, TrustHCP, TrustRelate, Validate, Workaround,
141	Sensitive	Sensitive/ity/ities	Describes or refers to sensitivities as related to privacy, information or communication	Boundaries, CommInhibit, CompImpact, Culture, DiscBarr, Distrust, Empathy, Fear, PrivManage, PrivRole, Security, TelePriv, Undocumented,
142	SideEffect	Side Effect/s	Refers to a current or potential side effect	Adherence, AE, ChronDis, CompRegs, Depress, DrugAdmin, FairBal, Oncology, OnLabel, PharmaTrust, Report, Safety, Stress,
143	Strategies	Strategies	Describes or refers to strategies or techniques used in education	Adherence, AssessPts, BehavChng, CommSkills, Defer, Demo, EngagePts, Fail, FairBal, Goals, HandlingLoss, HealthInfo, Holistic, Inject, Materials, Metric, Motivator, Notekeeping, PrivManage, PtShoes, Script, Security, SelfManage, Support, Tailoring, Validate, Workaround,
144	Stress	Stress	Refers to a Pt or CE feeling stressed or impacted by a stressful situation	Abandon, Adherence, Barrier, Behavior, CompImpact, Depress, Desperate, DisDefine, Distrust, DrugAdmin, Fail, FamDyna, Fear, Frustration, Inject, Insurance, Misconcept, Pregnant, PtEcon, Safety, SideEffect, TimeImpact, TrustBreach, Unprep,
145	Suicide	Suicide/s	Referencing suicide or suicidal ideation	Death, Depress, Desperate, Fear, Report, Safety,

146	Support	Support System/s	Describes or refers to a Pt's personal support systems or resources	AboveBey, Accessible, Adherence, AgeImpact, Barrier, CommInhibit, CommSkills, Community, Connect, Counsel, Culture, DiffMaker, DiscFacil, EdFam, Empathy, FamCare, Goals, HandlingLoss, HCPEngage, HCPRelate, HealthInfo, Holistic, LangLit, Motivator, Navigate, ProgBene, PtEcon, PtLeads, RelateDyna, Satisfaction, SelfAdvocate, SelfManage, Strategies, TrustDef, TrustHCP, TrustRelate,
147	Tailoring	Tailoring	Describes or refers to customization of patient education	AgeImpact, AssessPts, CommSkills, Counsel, Culture, EdFam, FldVPharm, Goals, Holistic, InfoSeek, InHome, Materials, ModImpact, ProfDev, PtLeads, Satisfaction, Script, Strategies, TimeImpact, TrngProc, TrngSet, Workaround,
148	Teach	Teach/er/es/ing	Describes or refers to being a teacher or teaching HCPs in formal education settings	CEBenefit, CERole, CommSkills, ExpLimit, LangLit, PersEx, ProfDev,
149	TeleEd	Telephonic Education	Related to CE education provided telephonically	CERole, Counsel, FTF, ModImpact, PrivSet, Script, TeleLimit, TelePriv, TrngSet, WebEd,
150	TeleLimit	Telephonic Limitation/s	Describes or refers to limitations that are related to telephonic education	CompExcess, DiscBarr, Fail, Frustration, ModImpact, ProtoBreach, Script, TeleEd, TelePriv, WebEd,
151	TelePriv	Telephonic Privacy	Describes or refers to issues of privacy related to telephonic Pt education	DiscBarr, DiscFacil, ModImpact, PrivManage, PrivSet, Sensitive, TeleEd, TeleLimit, TrustPriv, WebEd,
152	TermDis	Terminal Disease/s	Refers to a terminal disease	AutoImm, Cardiac, ChronDis, Death, Depress, Desperate, DisDefine, DisState, Fear, HandlingLoss, FairBal, ICU, Infusion, Neuro, Oncology, Parkinsons, RareDis,

153	TimeImpact	Time Impact	Describes how time, or lack of time, impacts or influences education	FTF, HCPEngage, InfoSeek, ModImpact, OpenComm, Stress, Tailoring, TrngProc, Unprep,
154	TrngProc	Training Process/Training Protocol	Descriptions or explanations of the training process, protocols or their components	Boundaries, CommSkills, CompImpact, CompRegs, Consistency, Counsel, Demo, DrugAdmin, EdFam, EngagePts, Enroll, FairBal, FamCare, Goals, Holistic, Materials, Metric, ModImpact, Navigate, OnLabel, PharmaOps, ProgReco, Script, Tailoring, TimeImpact, TrngSet, WebEd,
155	TrngSet	Training Setting/s	Describes or refers to the physical location where CE trains Pts.	EdFam, FamCare, FldVPharm, FTF, InHome, PrivSet, Tailoring, TeleEd, TrngProc, WebEd,
156	TrustBreach	Trust Breach/es/ing	Refers to situation or experience in which trust has, or is at risk, of being breached	CEIndep, CommInhibit, CompExcess, CompImpact, DiscBarr, Distrust, DrugScrutiny, Fear, Frustration, Manipulating, PharmaTrust, PrivBreach, PrivManage, ProtoBreach, Stress, TrustDef, TrustRelate, Unethical,
157	TrustDef	Trust Defined/Trust Definition	Refers to when a CE or Pt describes or defines the concept of trust	Balance, Connect, Empathy, EngagePts, PtShoes, Rapport, RelateDyna, Respect, Support, TrustBreach, TrustEarned, TrustHCP, TrustPriv, TrustRelate, TrustSac,
158	TrustEarned	Trust Earned	Describes or refers to the process of earning (or losing) trust	Accept, Accountable, Connect, DiscCE, DiscFacil, Empathy, EngagePts, Fail, LovePts, Motivator, PrivManage, ProgBene, Protect, Rapport, Satisfaction, SelfAdvocate, TrustDef, TrustHCP, TrustPriv, TrustRelate, TrustSac, Validate,
159	TrustHCP	Trust/s Healthcare Provider/s	Related to an expectations or instance of trust of Pt or CE toward HCP	Accept, DrugScrutiny, Empathy, HCPConsent, HCPEngage, HCPFeedback, HCPRelate,

				LangLit, Respect, SelfManage, Support, TrustDef, TrustEarned, TrustRelate,
160	TrustPriv	Trust Privacy	Refers to notion that privacy between Pt and CE is related to trust	Consent, DiscBarr, DiscCE, DiscFacil, PrivManage, PrivRole, TelePriv, TrustDef, TrustEarned, TrustRelate,
161	TrustRelate	Trust Relate/Trust Relationship	Describes or refers to the role of trust in the CE/Pt relationship	Accept, Balance, CEIndep, CERole, CommSkills, Connect, Counsel, Culture, DiffMaker, DiscBarr, DiscCE, DiscFacil, DrugScrutiny, Empathy, EngagePts, ExpLimit, Goals, Holistic, LovePts, Motivator, Navigate, PersEx, Rapport, RelateDyna, Respect, Satisfaction, SelfAdvocate, SelfManage, Support, TrustBreach, TrustDef, TrustEarned, TrustHCP, TrustPriv, TrustSac,
162	TrustSac	Trust Sacrifice/d/Trust Sacrificing	Describes or refers to when a sacrifice is required to build trust between CE & Pt.	Barrier, Behavior, Defer, PrivBreach, ProtoBreach, SavingFace, TrustDef, TrustEarned, TrustRelate, Workaround,
163	Undoc	Undocumented	Related to purposefully not making, or the inability to make, documentation	AE, CompExcess, Data, Enroll, Liability, Notekeeping, Report, Sensitive, Unethical,
164	Unethical	Unethical	Related to action or communication by CE or HCP that violates ethics	Boundaries, Distrust, Frustration, Liability, Manipulating, PharmaTrust, PrivBreach, Safety, TrustBreach, Undocumented,
165	UninhibDisc	Uninhibited Disclosure/s	Refers to a disclosures from Pts provided with little or no inhibitions	Boundaries, CommInhibit, Connect, DiscCE, DiscFacil, FamDyna, Holistic, LangLit, OpenComm,
166	Unprep	Unprepared	Refers to patient not receiving suitable education to self-manage	Barrier, Consistency, Desperate, DrugAdmin, ExpLimit, Fail, Frustration, Holistic, InfoSeek, Misconcept, Safety, SavingFace, Stress, TimeImpact,

167	Validate	Validate/s	Related to CE or HCP reaffirming or validating Pt beliefs, fears, barriers, et.	Accept, AssessPts, Connect, Counsel, DisDefine, Fear, HandlingLoss, Motivator, PersEx, ProgBene, PtKnow, PtShoes, Respect, SelfManage, Strategies, TrustSac,
168	WebEd	Web Education/ing	Describes or refers to Pt education delivered over the web	CommSkills, FTF, ModImpact, Script, TeleEd, TeleLimit, TelePriv, TrngProc, TrngSet,
169	Workaround	Workaround/s	Refers to manner in which CE works around a regulation or barrier	AboveBey, CompRegs, Culture, Defer, Goals, Liability, ModImpact, Navigate, OnLabel, ProfDev, ProgBene, Protect, SavingFace, SelfManage, Strategies, Tailoring, TrustSac,

Second-level Codes

PARENT GROUP	LONG NAME	SHORT NAME	DEFINITION
ROLE PERCEPTION		**ROLEPERC**	**How a clinical educator perceives their role within the healthcare field**
	Field Role defined	**RPFieldDef**	CE's perception of their role when working in the field (non-pharma)
	Pharma Role defined	**RPPharmDef**	CE's perception of their role when working on behalf of pharma or biotech
	Field vs Pharma	**RPFldVPharm**	CE comparing their field role to their pharma role
	Surrogate HCP/Conciliator	**RPSurrogate**	CE's perception of them serving as a surrogate clinician for Pt's HCP
	A Fellow patient	**RPFellowPt**	CE perception of their role while experiencing same/similar disease as the Pts they engage with
	Terminal Disease CE role	**RPTermDis**	CE's perception of their role working on behalf of pharma for terminal disease
	Telephonic CE role	**RPTelephonic**	CE's perception of their role as a telephonic educator
AUTHENTIC NURSING		**AUTHNURS**	**Perceptions of [how, why, why don't] pharma-sponsored CE's practice authentic nursing**
	CE sees self	**ANCESelf**	Related to [how, why, why don't] CEs consider themselves to practice authentic nursing

	Patient sees CE	**ANPtCE**	Related to [how, why, why don't] patients consider CEs to practice authentic nursing as interpreted by the CE
	Family sees CE	**ANFamCE**	Related to [how, why, why don't] patients' families consider CEs to practice authentic nursing as interpreted by the CE
	HCP sees CE	**ANHcpCE**	Related to [how, why, why don't] HCPs consider CEs to practice authentic nursing as interpreted by the CE
	Pharma sees CE	**ANPharmCE**	Related to [how, why, why don't] Pharma Co's consider CEs to practice authentic nursing as interpreted by the CE
CPM CONFIDANT ROLES TO PTs		**CPMROLEPT**	**A CE fulfilling a confidant role to Pts as defined by CPM**
	Deliberate	**RolePTDelib**	Exemplifies a CE fulfilling a deliberate confidant role to Pts as defined by CPM
	Reluctant	**RolePTReluct**	Exemplifies a CE fulfilling a reluctant confidant role to Pts as defined by CPM
	Stakeholder	**RolePTStake**	Exemplifies a CE fulfilling a stakeholder confidant role to Pts as defined by CPM
CPM CONFIDANT ROLES TO HCPs		**CPMROLEHCP**	**A CE fulfilling a confidant role to HCPs as defined by CPM**

	Deliberate	**RoleHCPDelib**	Exemplifies a CE fulfilling a deliberate confidant role to HCPs as defined by CPM
	Stakeholder	**RoleHCPStake**	Exemplifies a CE fulfilling a stakeholder confidant role to HCPs as defined by CPM
DUAL LOYALTY		**DUALLOYAL**	**A CE is caught between their loyalty to their patient and loyalty to other related stakeholders**
	Ethical Dilemma	**DLEthDil**	Exemplifies a CE's perception of being caught in an ethical dilemma
	Patient vs Pharma	**DLPtVPharm**	Exemplifies a CE's dual loyalty conflict between their Pt and their Pharma Co
	Patient vs HCP	**DLPtVHcp**	Exemplifies a CE's dual loyalty conflict between their Pt and the Pt's HCP
	Patient vs Family/caregiver	**DLPtVFam**	Exemplifies a CE's dual loyalty conflict between their Pt and the Pt's family
FUNCTION OF TRUST		**TRUST**	**Related to the the role or function of trust in the CE relationship w/ Pts, HCPs, family, or Pharma Co**
	Defining trust	**TRUSTDefine**	CE's interpretation of what trust is as it relates to their relationship w/ Pts, HCPs, family, or Pharma Co

	Earning trust	**TRUSTEarn**	CE's interpretation of how trust is earned as it relates to their relationship w/ Pts, HCPs, family, or Pharma Co
	Breaching trust	**TRUSTBreach**	CE's interpretation of how trust is breached as it relates to their relationship w/ Pts, HCPs, family, or Pharma Co
NUANCED COMMUNICATION		**NUANCED**	**CE using a communication strategy or nuancing their language to overcome a communication barrier**
	Defer to HCP	**NUDefer**	Exemplifies the CE deferring a patient to their HCP for additional help or information
	Off-label	**NUOffLabel**	Exemplifies a CE using nuanced communication to deal with off-label information requests
	Fair Balance	**NUFairBal**	Exemplifies a CE using nuanced communication to present fair balanced information
	Adverse Event	**NUAdverse**	Exemplifies a CE using nuanced communication to handle adverse event reports
	Liability protection	**NULiability**	Exemplifies a CE relating nuanced communication to legal issues or liability protection
	Navigating regulations	**NUNavigate**	Exemplifies a CE relating nuanced communication to navigating compliance regulations

	Telephonic navigation	**NUTelephonic**	Exemplifies a CE using nuanced communication to overcome telephonic limitations
	Disease/treatment barriers	**NUBarriers**	Exemplifies a CE using nuanced communication to overcome a disease or treatment barrier
PRIVACY MANAGEMENT		**PRIVMGMT**	**Related to the the role or manner in which privacy is mangaged in the CE relationship w/ Pts, HCPs, family, or Pharma Co**
	Defining privacy	**PMDefine**	CE's interpretation of what privacy is as it relates to their relationship w/ Pts, HCPs, family, or Pharma Co
	Protecting privacy	**PMProtect**	CE's interpretation of how privacy is protected as it relates to their relationship w/ Pts, HCPs, family, or Pharma Co
	Breaching privacy	**PMBreach**	CE's interpretation of how privacy is breached as it relates to their relationship w/ Pts, HCPs, family, or Pharma Co
ECOLOGICAL: CULTURAL		**ECOCULT**	**Describes or is related to the cultural context of the ecological model in the CE relationship w/ Pts**
	Religion	**CULTReligion**	Exemplifies religion as an influencing factor in the CE relationship w/ Pts
	Race/Ethnicity	**CULTRace**	Exemplifies race or ethnicity as an influencing factor in the CE relationship w/ Pts

	Age	**CULTAge**	Exemplifies age as an influencing factor in the CE relationship w/ Pts
	Gender	**CULTGender**	Exemplifies gender as an influencing factor in the CE relationship w/ Pts
	SES	**CULTEcon**	Exemplifies socioeconomic status as an influencing factor in the CE relationship w/ Pts
	Language	**CULTLang**	Exemplifies language/non-English fluency status as an influencing factor in the CE relationship w/ Pts
	Education	**CULTEduc**	Exemplifies educaation level as an influencing factor in the CE relationship w/ Pts
ECOLOGICAL: MEDIA		**ECOMEDIA**	**Describes or is related to the media context of the ecological model in the CE relationship w/ Pts**
	Education & Health Literacy	**MEDIALit**	Exemplifies education and/or health literacy as an influencing factor in the CE relationship w/ Pts
	Telephonic & web comm	**MEDIATele**	Exemplifies use of telephone or web-conferencing as an influencing factor in the CE relationship w/ Pts
ECOLOGICAL: ORGANIZATIONAL		**ECOORG**	**Describes or is related to the organizational context of the ecological model in the CE relationship w/ Pts**

	Insurance	**ORGInsur**	Exemplifies health insurance as an influencing factor in the CE relationship w/ Pts
	Health system bureaucracy	**ORGBureau**	Exemplifies health sytem bureauocracy as an influencing factor in the CE relationship w/ Pts
ECOLOGICAL:LEGAL/POLITICAL		**ECOLEGAL**	**Describes or is related to the legal/political context of the ecological model in the CE relationship w/ Pts**
	Compliance regs (general)	**LEGALCompReg**	Exemplifies the general nature of compliance regulations as an influencing factor in the CE relationship w/ Pts
	On label	**LEGALOnLab**	Exemplifies the necessity of maintaining on-label compliance as an influencing factor in the CE relationship w/ Pts
	Fair Balance	**LEGALFairBal**	Exemplifies the necessity of fair balance presentation as an influencing factor in the CE relationship w/ Pts
	AE reporting	**LEGALAdverse**	Exemplifies the necessity of adverse event reporting as an influencing factor in the CE relationship w/ Pts
ECOLOGICAL: EVERYDAY TALK		**ECOET**	**Describes or is related to the everyday talk of the ecological model in the CE relationship w/ Pts**

	Family dynamics	**ETFamDyna**	Exemplifies a Pt's family dynamics as an influencing factor in the CE relationship w/ Pts
	Community dynamics	**ETCommunity**	Exemplifies a Pt's community dynamics as an influencing factor in the CE relationship w/ Pts
DISEASE CONTEXT		**DISCONTEXT**	**Describes or is related to the role or impact of the disease in the CE communication relationship w/ Pts**
	Chronic vs Terminal	**DCChronVTerm**	Exemplifies a disease's chronic or terminal status as an influencing factor in the CE relationship w/ Pts
	Disease Side Effects	**DCDisSideEff**	Exemplifies a disease's symptoms or side effects as an influencing factor in the CE relationship w/ Pts
	Treatment Side Effects	**DCTreatSideEff**	Exemplifies a disease treatment's side effects as an influencing factor in the CE relationship w/ Pts
	Pregnancy	**DCPreg**	Exemplifies a Pt's pregnancy or motherhood status as an influencing factor in the CE relationship w/ Pts
	Drug Admin Modality	**DCAdmMod**	Exemplifies a disease treatment's administration modality as an influencing factor in the CE relationship w/ Pts
	Disabilities/Comorbidities	**DCDisCo**	Exemplifies a Pt's disability or comorbid conditions as an influencing factor in the CE relationship w/ Pts

	Disease Journey	**DCJourney**	Exemplifies where the patient is in their disease journey as an influencing factor in the CE relationship w/ Pts

Chapter 8: References

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Curriculum Vitae

Timothy Allen Barshinger

Education

Ph.D., Indiana University, 2020

Indiana University Purdue University Indianapolis

Major: Health Communication, Minor: Health Informatics

M.S.Ed., Purdue University, 1999

Purdue University, West Lafayette, IN

Major: Science Education, Emphasis: Distance Learning

B.S.Ed., Indiana University of Pennsylvania, 1992

Indiana University of Pennsylvania, Indiana, PA

Major: Elementary Education

Scholarships & Awards

Academy of Communication in Healthcare (May 2018)

$500 Health Equity Scholarship recipient

Petronio-Bantz Graduate Student Travel Award (May 2018)

$500 Travel scholarship for national conference

United States Distance Learning Association (October 2006)

21st Century Award for Best Practices PreK-12 Videoconferencing

Silver Award for Best Practices in Distance Learning Programming

The Honor Society of Phi Kappa Phi (August 1997)

Invited member of national academic honor fraternity, Purdue University Chapter.

Center for Interactive Learning & Collaboration "Vision Athena" Fellowship (June 1997)

Founding fellow and recipient of $5,000 award to conduct Master's research

National Audubon Society (August 1994)

Ecology Training Scholarship recipient

Clarion University of PA (July 1991).

Pennsylvania Science Teachers Enhancement Program for Pre-service Elementary School Teachers

Grants

National Science Foundation Grant, Award # 0337204 (January 2005)

Grant author and Principal Investigator for $1.6 million Informal Science Education award.

Led creation and management of a multi-participant national distance learning collaboration that developed and assessed the feasibility of an original series of anatomy, physiology and health science education programs disseminated via interactive video and online technologies to school-age children. Managed all day-to-day operation of the partnership. Oversaw all budget expenditures and managed staff of 6 individuals

The Lilly Endowment Inc. Grant (December 1998)

Grant author, co-investigator and project manager for $620,000 grant to Perry Township Education Foundation for JASON Indiana.

South Bend Audubon Society's Woolman-Groet-Miller Fund (May 1994)

$500 award for purchase of environmental lab equipment for Elm Road Elementary School.

Publications

Barshinger, T.A. (2019, August) *Care coordination & education impact patient outcomes in integrated health systems.* Whitepaper authored on behalf of VMS BioMarketing: Indianapolis, IN.

Barshinger, T.A. (2000, February). "*A tour before": Interpretations of a science gallery & the interactive videoconference which preceded it.* Published in the Proceedings of the

annual conferences of Mathematics/Science Education & Technology (MSET): San Diego, CA.

Barshinger, T.A. & Ray, A. (1998, August) *From volcanoes to virtual tours: Bringing museums to students through videoconferencing technology*. Published in the Proceedings of the 14th Annual Conference on Distance Teaching & Learning.

Barshinger, T.A. (1998, January) *Museum & Methods Collaboration: Understanding Science Teaching Via Distance Learning Technology*. Published in the Proceedings of the 1998 Association for the Education of Teachers of Science (AETS) Annual Meetings.

Barshinger, T.A. (1998, March) *Volcanoes to "virtual tours": bringing museums to children via videoconferencing*. Published in the Proceedings of the 1998 Society for Information Technology & Teacher Education Annual Meeting.

Conferences and Invited Presentations

Barshinger, T.A. (2019, October). *Communication experiences of therapy-sponsored clinical educators (A work-in-progress*). Oral presentation to be presented at the International Conference on Communication in Healthcare, San Diego, CA.

Barshinger, T.A., Holden, H., & Moscatiello, T. (2018, June). *Education challenges and strategies for complex self-administered medication therapies: Adapting to patient needs*. Workshop presented at the Academy of Communication in Healthcare Research Forum, Tampa, FL.

Barshinger, T.A. (2018, June). *Protection and adherence ideologies in FDA medication labeling requirements: Navigating the impact on patient education*. Poster presented at the Academy of Communication in Healthcare Research Forum: Tampa, FL.

Petronio, S. & Barshinger, T.A. (2017, June) *Using Communication Privacy Management (CPM) theory to interpret the communication experiences of pharmaceutical and biotech company-sponsored patient navigators: A work in progress*. Oral presentation presented

at the 15th International Conference on Communication, Medicine, and Ethics (COMET): Indianapolis, IN.

Barshinger, T.A. (2017, June) *Healthcare professionals' education engagement as a predictor of patient activation in diabetes.* Poster presented at the 15th International Conference on Communication, Medicine, and Ethics (COMET): Indianapolis, IN.

Barshinger, T.A. (2007, June). *Distance edutainment is here!* Paper presented at the annual National Education Computing Conference (NECC): Philadelphia, PA.

Barshinger, T.A. & Midland, D. (2006, October) *Distance edutainment: Collaborating to deliver programming to family audiences through interactive video technology*. Paper presented at the annual Association of Science & Technology Centers Conference: Louisville, KY.

Barshinger, T.A. (2006, September). *Grossology LIVE: Teaching innovative health programming via distance learning technologies.* Invited oral presentation presented to the Centers for Disease Control & Prevention-Division of Adolescent & School Health: Atlanta, GA.

Barshinger, T.A. (2005, June) *Diving into something really gross*. Oral presentation presented at the annual National Education Computing Conference (NECC): Philadelphia, PA.

Barshinger, T.A. & Midland, D. (2004, September). *Implementing & marketing your distance learning initiatives*. Oral presentation presented at the annual National Association of Health Education Centers Conference: Cleveland, OH.

Barshinger, T.A. (2003, June). *Dynamic distance learning*. Oral presentation presented at the annual National Educational Computing Conference (NECC): Seattle, WA.

Barshinger, T.A. (2002, August). *Distributed learning.* Oral presentation presented at the annual National Association of Health Education Centers Conference: Cleveland, OH

Barshinger, T.A. (2002, June). Dynamic distance learning. Paper presented at the Annual Conference on Distance Learning & Teaching: Madison, WI.

Barshinger, T.A. (2002, June). *Go a greater distance with distance learning*. Full-day workshop presented at the annual National Educational Computing Conference (NECC): San Antonio, TX

Bartlett, K. & Barshinger, T.A. (2000, June). *Videoconferencing innovations and issues: Museums and their K-12 colleagues.* Oral presentation presented at the annual National Educational Computing Conference (NECC): Atlanta, GA.

Barshinger, T.A. (1999, March). "*A Tour Before": Interpretations of a science gallery & the interactive videoconference which preceded it*. Paper presented at National Association for Research in Science Teaching: Boston, MA.

Bartlett, K. & Barshinger, T.A. (1998, January) *Museum & methods collaboration: Understanding science teaching via distance learning technology*. Paper presented at the annual conferences of the Association for the Education of Teachers of Science: Minneapolis, MN.

Ray, A. & Barshinger & Barshinger, T.A. (1999, February) *Distance learning connections: Linking schools & content providers via a videoconferencing network.* Paper presented at the annual conferences of the Association for Educational Communications & Technology: Houston, TX.

Bartlett, K. & Barshinger, T.A. (1998, April) *Interpretations of a visit to a museum following a two-way audio/visual interactive learning (2WAVIL) link*. Paper presented at the annual conference of the National Association for Research in Science Teaching: San Diego, CA (1998, April).

Barshinger, T.A. & Ray, A. (1998, January) From volcanoes to virtual tours: Bringing museums to students through videoconferencing technology. Paper presented at the Annual Conference on Distance Learning & Teaching: Madison, WI.

Professional organization memberships

Academy of Communication in Healthcare (September 2017-present)

Served on *Patient Engagement* sub-committee (2017)

International Conference on Communication in Healthcare (September 2017-present)

Oral presentation session reviewer for 2019 Conference

Communication, Medicine & Ethics (May 2017-present)

Member

National Communication Association (November 2014-present)

Member

Science Education Foundation of Indiana [SEFI] (January 2009-January 2012)

Board Member for statewide organization whose purpose is to encourage and assist young people to become scientists and engineers and to practice their professions in Indiana

Indiana Science Alliance (2005-2006)

Career Development Advisory Committee Member for 2006 International Science & Engineering Fair in Indianapolis

International Society for Technology in Education (June 2000-December 2007)

National Educational Computing Conference (NECC): Co-chair—Interactive Videoconferencing Strand (2006 -2007)

National Educational Computing Conference (NECC): Lead Session Reviewer—IVC Showcase (2004-2006)

National Science Teacher Association (2005-2007)

Member

Hoosier Association of Science Teachers Inc (2005-2007)

Member

Indiana Computer Educators (2005-2007)

Member